DRG® Malaria pf/py Antigen Test (RAP-5092)

As of 9 Aug. 2010 **RUO**

A rapid test for the qualitative detection of Malaria pf and pv antigen in human blood sample

For in vitro use only

Intended Use

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

Summary

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 DRG® Malaria pf (HRP II) / pv (LDH) Antigen Test 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 specific to the lactate dehydrogenase of the *P. vivax* species (pvLDH). 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 specific to the lactate dehydrogenase of *P. vivax*. Therefore, the antigen of
Plasmodium falciparum and *Plasmodium vivax* can be differentially detected.

Precautions

- For professional *in vitro* use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

Storage & Stability

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The kit can be stored at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials Provided:

- Test Device
- Assay Buffer
- Instructions for Use

Materials Not Provided:

- Calibrated pipette
- Lancet
- Timer

Specimen Collection & Preparation

[Collection by venipuncture]

1) Collect whole blood into a collection tube (containing EDTA, citrate or heparin) by venipuncture.
2) If specimens are not immediately tested, they should be refrigerated at 2 ~ 8°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 ~ 8°C, the whole blood sample should be used within three days.
4) **[Collection using a lancet]**
5) Clean the area to be lanced with an alcohol swab.
6) Squeeze the end of the fingertip and pierce with a sterile lancet provided.
7) Wipe away the first drop of blood with sterile gauze or cotton.
8) Using the dropper provided, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the dropper.

Directions for Use:

Allow test device, buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1) Add 5 µl of whole blood into sample well [S], the small well.

2) Add two drops (80 µLs) of assay buffer into developer well marked with [ ]
3) Read the test result in 20 min.

Interpretation of Results:

(Please refer to the illustrations)

***1) P. falciparum* Positive Reaction**

The presence of two color bands, "C" and "1" indicates a positive result for *P. falciparum*.

***2) P. vivax* Positive Reaction**

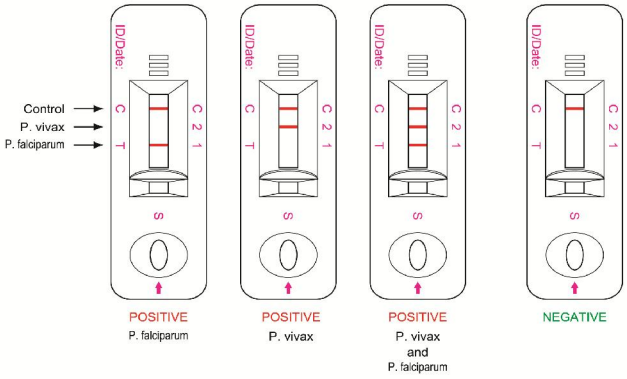
The presence of two color bands, "C" and "2" indicates a positive result for *P. vivax.*

3) *P. falciparum* and *P. vivax* Positive Reaction

The presence of three color bands indicates a positive result for *P. falciparum* and *P. vivax.*

4) Negative reaction

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



5) Invalid

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

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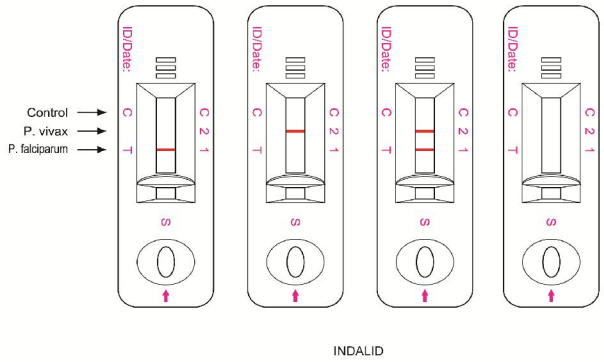

Limitations

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 pvLDH, 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.

Bibliography

1) Leonard K. Basco, Frederique Marquet, Michael M. Makler, and Jacques Le Bras. : *Plasmodium falciparum* and *Plasmodium vivax*: Lactate Dehydrogenase Activity and its Application for in vitro Drug Susceptibility Assay. Experimental Parasitology 80, 260-271 (1995)
2) 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.
3) David J. Bzik, Barbara A, Fox and Kenneth Gonyer : Expression of *Plasmodium falciparum* lactate dehydrogenase in *Escherichia coli* Molecular and Biochemical Parasitology, 59(1993) 155-166
4) 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

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5) 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
6) 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
7) 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
8) 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

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