



**Malaria Test Cassette**

Human Malaria Antigen

Rapid Cassette Test (Whole blood)

A rapid test for the qualitative detection of Human Malaria antigen in whole blood

**Not for sale in USA**

**INTENDED USE**

For the rapid qualitative determination of Malaria lactate dehydrogenase in human blood as an aid in the diagnosis of Malaria infection.

**SUMMARY**

Malaria is a serious, sometimes fatal, 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.

The Malaria Antigen Test includes a membrane that is pre-coated with two monoclonal antibodies as two separate lines test cassette. One monoclonal antibody (test line 1) is specific to the lactate dehydrogenase of *P. falciparum* and another monoclonal antibody (test line 2) is pan specific to the lactate dehydrogenase of Plasmodium species (*P. falciparum*, *vivax*, *malariae*, *ovale*). The conjugate pad is dispensed with monoclonal antibody, which is pan specific to the lactate dehydrogenase of *Plasmodium* species.

The Malaria Antigen Test is designed for the differential diagnosis of *Plasmodium falciparum* and the other *Plasmodium* species.

Materials provided

Malaria Antigen Test Kit contains the following items to perform the assay:

- Test Cassette
- Assay Buffer
- Sample pipette

**PRECAUTIONS**

- 1) For *in vitro* diagnostic use only.
- 2) Use disposable gloves while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards.
- 3) Do not use product after the expiration date.
- 4) Do not eat or smoke while handling specimens.
- 5) Clean up spills thoroughly using an appropriate disinfectant.
- 6) Humidity and high temperature can adversely affect results.

**SPECIMEN COLLECTION AND STORAGE**

**Collection by venipuncture**

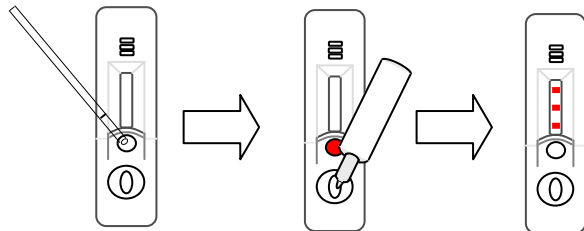
- 1) Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by venipuncture.
- 2) If specimens are not immediately tested, they should be refrigerated at 2-8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen in the long-term keeping 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.

**Collection using a lancet**

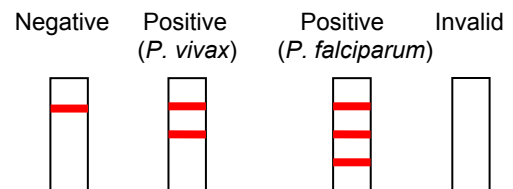
- 1) Clean the area to be lanced with an alcohol swab.
- 2) Squeeze the end of the fingertip and pierce with a sterile lancet provided.
- 3) Wipe away the first drop of blood with sterile gauze or cotton.
- 4) Using the dropper provided, while gently squeezing the tube, immerse the open tip in the blood drop then gently release the pressure to draw blood into the tube.

**TEST PROCEDURE**

- 1) Dispense 5 µl of whole blood to the (**upper**) port of the cassette as shown.
- 2) Add 2 drops of assay buffer to the (**lower**) port of the cassette as shown below.
- 3) Read the test cassette after 20 minutes.



**INTERPRETATION OF THE TEST**



**1) *P. falciparum* positive reaction**

The presence of three color bands or two color bands (control band and bottom test band) indicates a positive result for *P. falciparum*. The pLDH present in the sample reacts with the pan anti-pLDH conjugate and moves up the Test Cassette where the pLDH is captured by both *P. falciparum*-specific anti-pLDH and pan specific anti-pLDH.

## 2) *P. vivax* or other *Plasmodium* sp. positive reaction

The presence of two color bands indicates a positive result for *P. vivax* or other *Plasmodium* sp. The pLDH present in the sample reacts with the pan anti-pLDH conjugate and rises up the Test Cassette where the pLDH is captured by pan-specific anti-pLDH.

## 3) Negative reaction

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

## 4) Invalid

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

## LIMITATIONS AND INTERFERENCES

- 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* 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 pLDH, 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.

## PERFORMANCE CHARACTERISTICS

The Malaria Antigen rapid test has been tested with positive and negative clinical specimens previously tested by microscopic examination.

### 1) Malaria *P. vivax* evaluation results

	<i>P. vivax</i> -positive confirmed specimen		Sensitivity
	Positive	Negative	
<b>Malaria Ag Rapid</b>	89	11	89%

### 2) Malaria *P. falciparum* evaluation results

	<i>P. falciparum</i> -positive confirmed specimen		Sensitivity
	Positive	Negative	
<b>Malaria Ag Rapid</b>	90	10	90%

### 3) Malaria-negative human specimen evaluation results

	Random normal human specimen		Specificity
	Positive	Negative	
<b>Malaria Ag Rapid</b>	1	199	99.5%

Within run and between run precision was determined by testing 10 replicates of three specimens: a negative, a low positive and a strong positive. The agreement between the test results and the expected results was 100%.

## 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