Atlas Medical

CE

Malaria Pf/Pv Test
Rapid Cassette Test (Whole blood)

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

IVD *For in vitro diagnostic use only*

2 ~ 30°C Store at 2-30 °C

INTENDED USE

For the rapid qualitative determination of Malaria lactate dehydrogenase (LDH) and Malaria histidine rich protein-2 (HRP-2) in human blood as an aid in the diagnosis of Malaria infection

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 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 Histidine rich protein-2 of *P. falciparum* and another monoclonal antibody (test line 2) is pan specific to the lactate dehydrogenase of P.vivax . Conjugate pad is dispensed with monoclonal antibody, which is pan specific to the lactate dehydrogenase of *Plasmodium species.*

So the Malaria Antigen Test is designed for the differential diagnosis between *Plasmodium falciparum* and the other *Plasmodium species*

MATERIALS

MATERIALS PROVIDED

- Test card individually foil pouched with desiccant
- Plastic dropper
- Buffer
- Package insert

MATERIALS NOT PROVIDED

- Positive and negative controls

PRECAUTION

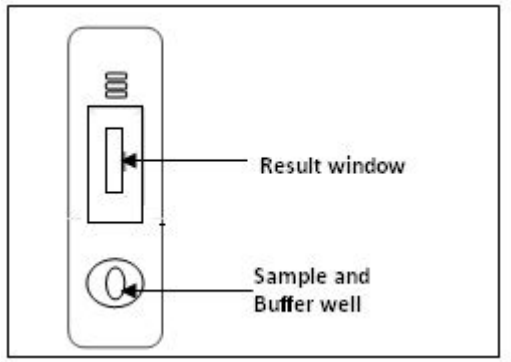
- For in vitro diagnostic use only.
- Use disposable gloves while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards.
- Do not use beyond the expiration date.
- Do not eat or smoke while handling specimens.
- Clean up spills thoroughly using an appropriate disinfectant.

SPECIMEN COLLECTION AND STORAGE

- **[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.

- **[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 end in the blood drop and then gently release the pressure to draw blood into the dropper.

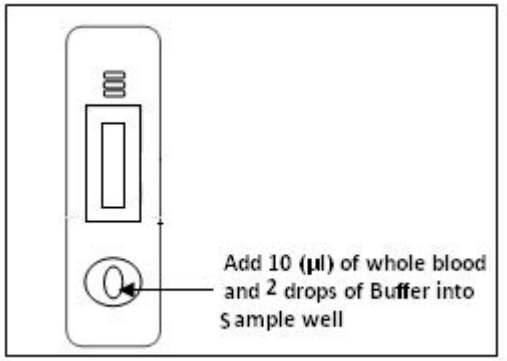
PROCEDURE



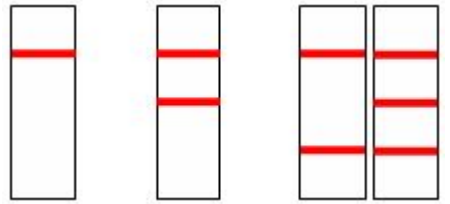
1) Add 1 Drop (10 µl) of whole blood into sample well of the test card using the plastic dropper provided according to the figure.
2) Add 2 drops (100 µl) of buffer to the "s" well after the specimanis added .
3) Interpet the results at 20 minutes.

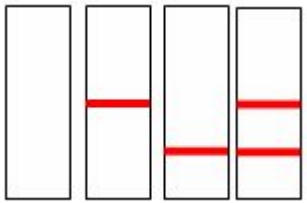
Notes :

Do not interpet result after 30 minutes.



INTERPRETATION OF TEST





Invalid

1. **P. falciparum Positive reaction:** The presence of two color bands (C-line and T1) indicates a positive result for P.falciparum.
2. **P. vivax Positive reaction :** The presence of two color bands (C-line and T2 line) indicates a positive result for P. vivax .
3. **P.falciparum and P.vivax reaction:** The presence of three control bands (C-line ,T1,and T2) Indicates a positive result for P.falciparum and P.vivax.
4. **Negative reaction** The presence of only one band (c-line) within the result window indicates a negative result.
5. **Invalid** The test is invalid if the C line does not appear. If this occurs, the test should be repeated using a new strip.

LIMITATIONS AND INTERFERENCES

- The test procedure, precautions and interpretation of results for this test must be followed when testing.
- Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
- This test kit detects Plasmodium lactate dehydrogenase and histidine rich protein-2 in patient whole blood and is useful as a screening procedure of malaria diagnosis.
- Do not mix reagent of different lots.
- The test is limited to the detection of antigen to Malaria *Plasmodium sp.* Although the test is very accurate in detecting pLDH and HRP-2, 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 AND CHRACTERISTICS

The Malaria Antigen rapid kit as tested with positive and negative clinical samples tested by microscopic examination of whole Blood

1) Malaria *P. vivax* evaluation results

	P.v-positive confirmed specimen		Sensitivity
	Positive	Negative	
Malaria Ag Rapid	89	11	89/100 x 100% = 89%

2) Malaria *P. falciparum* evaluation results

	P.f-positive confirmed specimen		Sensitivity
	Positive	Negative	
Malaria Ag Rapid	90	10	90/100 x 100% = 90%

3) Malaria-negative normal human specimen evaluation results

	Random normal human specimen		Specificity
	Positive	Negative	
Malaria Ag Rapid	1	199	199/200 x 100%=99.5%

Precision

Within-run and between-run precisions have been determined by the 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 were 100%.

REFERENCES

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.

Atlas Medical
William James House, Cowley Rd,
Cambridge, CB4 4WX, UK
Tel: ++44 (0) 1223 858 910
Fax: ++44 (0) 1223 858 524

PPI345A01
Rev D (02.11.2015)

REF	**Product Reference No.**	IVD	**For in-vitro diagnostic use.**
	Caution.		**Store at**
	Read product insert before use.		**Number of tests in the pack.**
LOT	**Lot (batch) number.**		**Manufacturer.**
	Expiry date.		**Manufacturer telephone number.**
	Manufacturer fax number.		