

For the rapid qualitative determination of Malaria *P. falciparum* and Malaria *P. Vivax* in human blood.
Only for *In vitro* Diagnostics use

ORDER INFORMATION

REF	Cont.
MAGC 10	10 Test
MAGC 25	25 Test
MAGC 50	50 Test

CLINICAL SIGNIFICANCE

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.

PRINCIPLE

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 the *P. falciparum* histidine rich protein-2 (pf HRP II) and another monoclonal antibody (test line 2) is pan specific to lactate Dehydrogenase (Pan LDH) of plasmodium species (*P.Falciparum, Vivax, Malariae, Ovale*).** Conjugate pad is dispensed with monoclonal antibodies conjugated to the colloidal gold, which are specific to *P. Falciparum* histidine rich protein-2(pf HRP-II) and pan specific to the Lactate Dehydrogenase (Pan LDH) of other *Plasmodium* species.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and Product Insert

STORAGE & STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. **DO NOT FREEZE.**
- Do not use beyond the expiration date.
- Do not use the test kit, if the pouch is damaged or seal is broken.

PRECAUTIONS

- Wear protective gloves while handling specimens wash thoroughly afterwards.
- The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch before test.
- Do not mix reagents from different lot.
- Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
- Follow the testing procedure exactly as mention in the insert.

LIMITATIONS

- The test procedure, precautions and interpretation of results for this test must be followed when testing.
- The test is limited to the detection of antigen of 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.

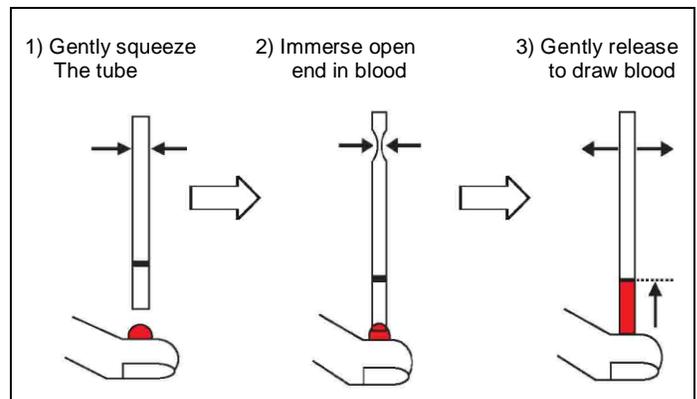
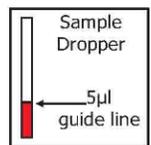
SPECIMEN COLLECTION & PREPARATION

- Use Blood samples collected from the venipuncture into a collection tube containing EDTA, citrate or heparin.
- If specimens are not immediately tested, they should be refrigerated at 2-8°C for up to three days before testing.
- Anticoagulant such as EDTA, Citrate or Heparin, do not affect the test report.

OR

Collection using a lancet

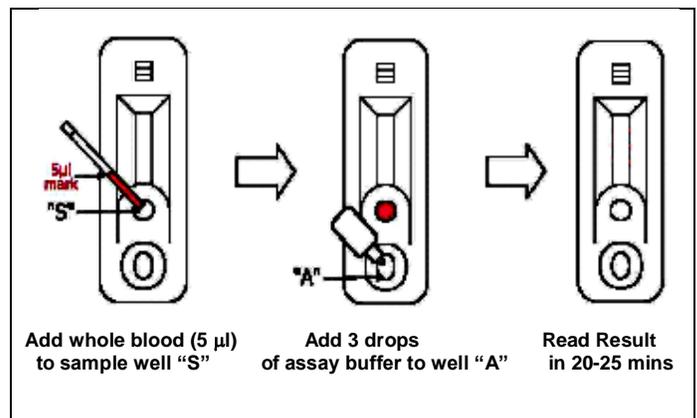
- Clean the area to be lanced with an alcohol swab.
- Squeeze the end of the fingertip and pierce with a sterile lancet.
- Wipe away the first drop of blood with sterile gauze or cotton.
- Take a sample dropper, and while gently squeezing the tube, immerse the open end in the blood drop and then gently release the



pressure to draw blood into the sample dropper upto the mark line.

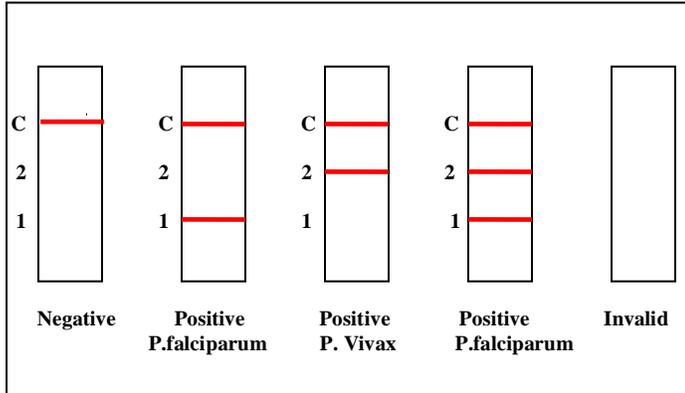
DIRECTIONS FOR USE

- Add 5µl of whole blood into sample well ("S" small well) (**Do not use excess blood**).
- Add 3 drops of assay buffer into developer well ("A").



- Read the test result at 20-25 mins

INTERPRETATION OF RESULTS



1. Negative reaction

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

2. P. falciparum Positive reaction

The presence of two color bands (C and 1) indicates a positive result for P. falciparum. The pf HRP II present in the sample reacts with the pf HRP II conjugate and move through the test strip where the pf HRP II is captured by the anti -P falciparum specific HRP II.

3. P. Vivax other Plasmodium sp. Positive reaction

The presence of two color bands (C and 2) indicates a positive result for P. vivax. The pLDH present in the sample reacts with the other malaria antigen anti-pLDH conjugate and moves through the test strip where the pLDH is captured by pan specific anti-pLDH.

4. P. falciparum and other Plasmodium sp. Positive reaction

The presence of 3 colored bands indicate a positive result for P. falciparum and P Vivax, The pf HRP II present in the sample reacts with the pf HRP II conjugate and move through the test strip where the pf HRP II is captured by the anti P.falciparum specific histidine rich protein 2 (pf HRP II) The pLDH present in the sample reacts with the pan anti pLDH conjugate and move through the test strip where the pLDH is captured by pan specific anti pLDH.

5. Invalid

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

PERFORMANCE CHARACTERISTICS

The malaria Pf/Pv antigen has been evaluated with positive negative sample Tested by microscopic examination.

	P.f.	Pv
Sensitivity	100 %	100 %
Specificity	99.8 %	

BIBLIOGRAPHY

- 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).
- David L. Vander, Jagt, Lucy A. Hunsaker and John E. Heidrich: Partial Purification and Characterisation of Lactate Dehydrogenase from Plasmodium falciparum. *Molecular and Biochemical Parasitology*, 4 (1981) 255-264.
- 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.
- 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.
- Howard, RJ, et al. The secretion of a Malaria Histidine-rich Protein (Pf HRP-2) from Plasmodium falciparum-infected Erythrocytes. *J. Cell Biol.*, (1986) 103, 1269-1277.
- Rock, EP, et al. Comparative Analysis of Plasmodium falciparum Histidine-Rich Protein - 2, HRP-I, HRP-II, and HRP-III in Malaria Parasitology Diverse Origin. *Parasitol.*, (1987) 95:209-27.
- Panna, ME, et al. Identification of Plasmodium falciparum Histidine-Rich Protein - 2 in the of Humans with Malaria. *J. Clin. Microbiological* 29:1629-1634.
- Rodriguez-del Valle, M. et al, Detecting Antigens and Antibodies in the Urine with Plasmodium falciparum Malaria. *Slit Microbiol.*, (1991) 29:1236-1242.