

For the rapid qualitative determination of Malaria *P. falciparum* (HRP2) and Malaria *P. vivax* (pLDH) in human whole blood

Store at 2-30°C. DO NOT FREEZE.
Only for *In vitro* Diagnostics use

For Laboratory and Blood Bank Use.

ORDER INFORMATION

REF	Cont.
MAGC 01	01 Test
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 malaria species: *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium Ovale* and *Plasmodium Malariae* which are responsible for malaria in the human population. In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites.

ACCUCARE® ONE STEP MALARIA Pf/Pv ANTIGEN RAPID TEST is a rapid, Point-of-care, qualitative, two-site sandwich immunoassay for the determination of Pf HRP2 and Pv pLDH in whole blood.

PRINCIPLE

The Malaria Antigen Test contains a nitrocellulose 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 HRP2) and another monoclonal antibody (Test line 2) is specific to *P. vivax* lactate Dehydrogenase (Pv pLDH) of plasmodium species. Conjugate pad is prepared with monoclonal antibodies conjugated to the colloidal gold, which are specific to *P. Falciparum* histidine rich protein-2 (Pf HRP2) and Pv specific to the Lactate Dehydrogenase (Pv pLDH). As the sample flows through the membrane assembly of the test, after addition of the diluent buffer, the anti-Pf HRP2 and anti-pLDH colored colloidal gold monoclonal antibody conjugates with the pLDH and Pf HRP2 if present in the lysed sample. This complex moves further along the membrane to the test region where it is immobilized by the anti-pLDH and anti-Pf HRP2 monoclonal antibodies coated on the membrane, leading to the formation of pinkish purple colored lines, which confirms a positive test result.

The unreacted conjugate, unbound complex (if any), and the colloidal gold conjugated Mouse IgG moves further along the membrane and is subsequently immobilized by the anti-Mouse IgG coated on the membrane at the control region, forming a pinkish purple line. This control line serves to validate the test performance.

CONTENTS

Test Device
Assay Buffer
Instruction for Use (IFU)
Disposable (Dropper) 5 µl sampling device
Desiccant

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 Instruction for Use.

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 HRP2 and 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.

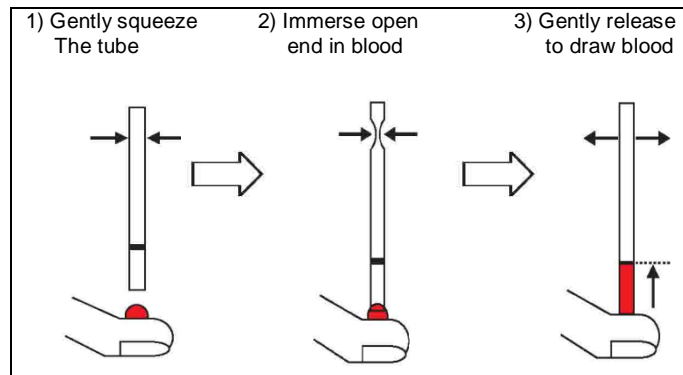
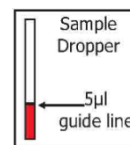
SPECIMEN COLLECTION & PREPARATION

- Capillary blood or venous blood with the following anticoagulant: EDTA, Heparin or Citrate can be used.
- If specimens are not tested immediately, they should be refrigerated at 2-8°C for upto three days.
- Anticoagulant such as EDTA, Citrate or Heparin, do not affect the test results.

SPECIMEN COLLECTION PROCEDURE

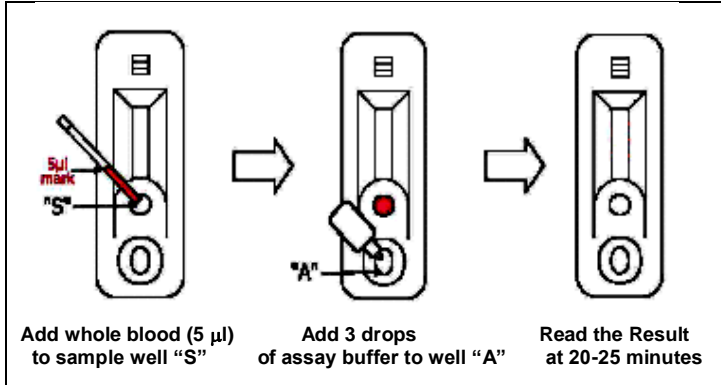
Capillary Blood Sample	Venous Blood Sample
<ul style="list-style-type: none"> Select the finger or thumb to be pricked and clean the fingertip with the sterile swab. Allow to dry thoroughly before proceeding with the blood collection. Remove the protective cap from the safety lancet and firmly push the safety lancet against the bulb of the finger. 	<ul style="list-style-type: none"> Mix the anti-coagulated blood sample by gently swirling.

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.

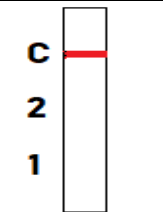
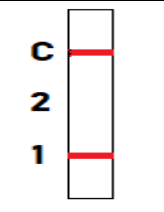
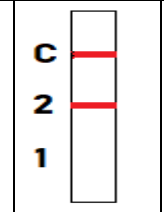
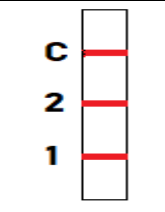


TEST PROCEDURE

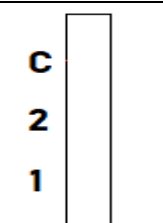
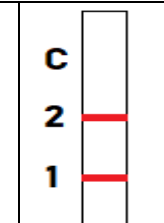
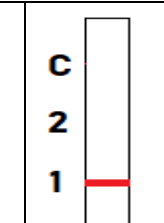
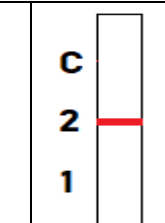
1. Add 5µl of whole blood into sample well ("S" small well) (**Do not use excess blood**).
2. Add 3 drops of assay buffer into developer well ("A").
3. Read the test result at 20-25 minutes. Do not interpret after 30 minutes.



INTERPRETATION OF RESULTS

			
Negative	<i>P. falciparum</i> Positive	<i>P. Vivax</i> Positive	<i>P. falciparum</i> + <i>P. Vivax</i> Positive

INVALID RESULTS

			
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1. Negative reaction

The presence of only one band at control region in result window indicates a negative result.

2. *P. falciparum* Positive reaction

The presence of two color bands one at 'C' region and one at region '1' indicates a positive result for *P. falciparum*.

3. *P. vivax* Positive reaction

The presence of two color bands one at 'C' region and one at region '2' indicates a positive result for *P. vivax*.

4. *P. falciparum* & *P. vivax* Positive reaction

The presence of three color bands one at 'C' region, one at region '1' and one at region '2' indicates a positive result for *P. falciparum* & *P. vivax*.

5. Invalid

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

INTERFERING SUBSTANCES

No interference in the ACCUCARE® ONE STEP MALARIA Pf/Pv ANTIGEN RAPID TEST was evident when the following substances were tested Albumin up to 20 mg/ml, Bilirubin up to 20µg/ml, Hemoglobin up to 15 mg/ml, Glucose up to 20 mg/ml, Uric Acid up to 200µg/ml, Lipids up to 20 mg/ml, Ascorbic Acid up to 200 mg/dL, Caffeine up to 200 mg, Ethanol up to 1.0 % and Methanol up to 10.0 %.

PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP MALARIA Pf/Pv ANTIGEN RAPID TEST has been evaluated with positive and negative samples confirmed by microscopic examination.










Specimen	Positive	Negative	Sensitivity
<i>P. falciparum</i>	57	03	95 %
<i>P. vivax</i>	240	00	100 %

Specimen	Positive	Negative	Specificity
Negative	08	352	97.8 %

BIBLIOGRAPHY

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2. 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.
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6. 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.
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GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For <i>in vitro</i> Diagnostic use only		Keep Dry
	Tests per Kit		Do Not Use if Damaged