

MALARIA Pf/Pv Ag TEST (Whole Blood)

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.
PMFV 01	1 Test
PMFV 05	5 Test
PMFV 10	10 Test
PMFV 25	25 Test
PMFV 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 (Pf) is specific to the *P. falciparum* histidine rich protein-2 (Pf HRP II) and another monoclonal antibody (Pv) is specific to lactate Dehydrogenase (Pv LDH) of *P. Vivax*.** 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 Pv specific to the Lactate Dehydrogenase (Pv 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.

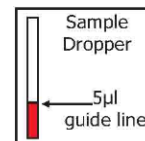
SPECIMEN COLLECTION & PREPARATION

- 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

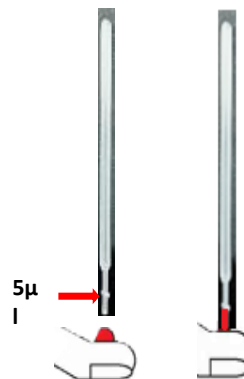
Collection using a lancet

- 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 up to the mark line.

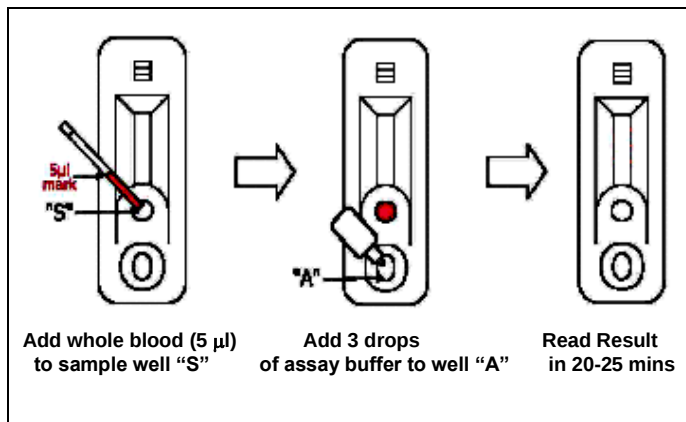


DIRECTIONS FOR USE

- Add 5µl of whole blood into sample well ("S" small well) (**Do not use excess blood**).

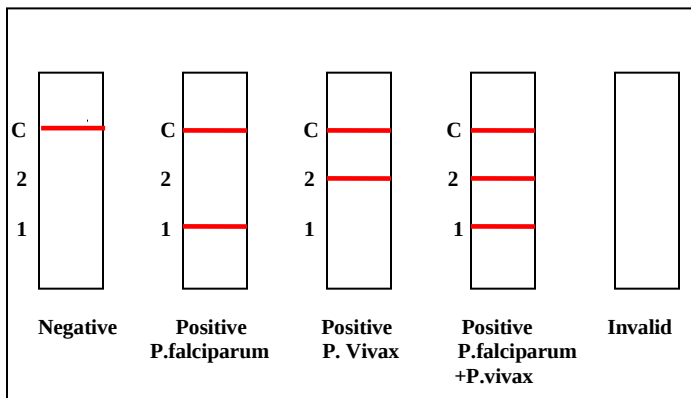


- Add 3 drops of assay buffer into developer well ("A").



- 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 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 Pv specific anti-pLDH.

4. P. falciparum and other P. Vivax 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 Pv anti pLDH conjugate and move through the test strip where the pLDH is captured by Pv 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 %	

Note: The Malaria Pf/Pv Antigen has sensitivity of 200 parasites/ μ l of whole blood at base line. The product has been studied and tested after 60 days at room temperature, 35°C and 45°C

BIBLIOGRAPHY

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- Pvna, ME, et al. Identification of Plasmodium falciparum Histidine-Rich Protein - 2 in the of Humans with Malaria. J. Clin. Microbiological 29:1629-1634.
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GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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