# 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).

### KIT COMPONENTS
Test Device, Assay Buffer, Sample Dropper and Product Insert.

### STORAGE & STABILITY

1. 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.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

### PRECAUTIONS

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

### LIMITATIONS

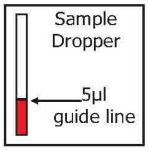
1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The test is limited to the detection of antigen of Malaria Plasmodium sp. Although the test is very accurate in detecting pLDH, a low incidence of false results can occur. Other clinically 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

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

**OR**

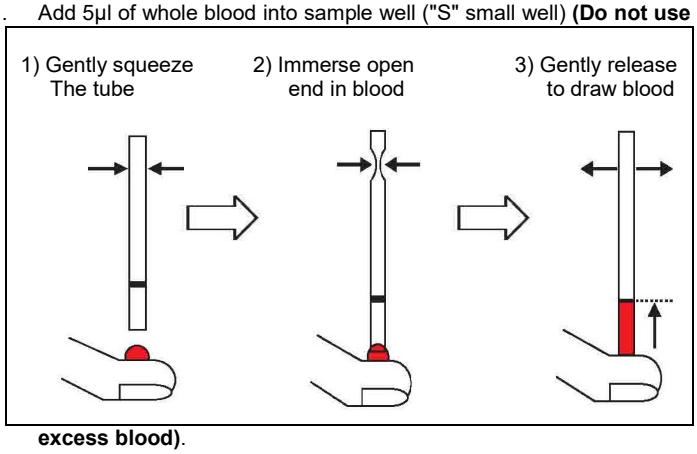
**Collection using a lancet**



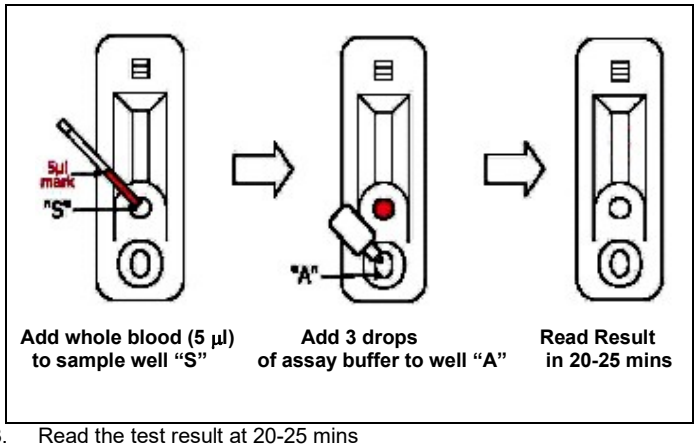

1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Take a sample dropper, and while gently squeezing the tube, immerse the open end in the blood drop and then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

### DIRECTIONS FOR USE

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 mins

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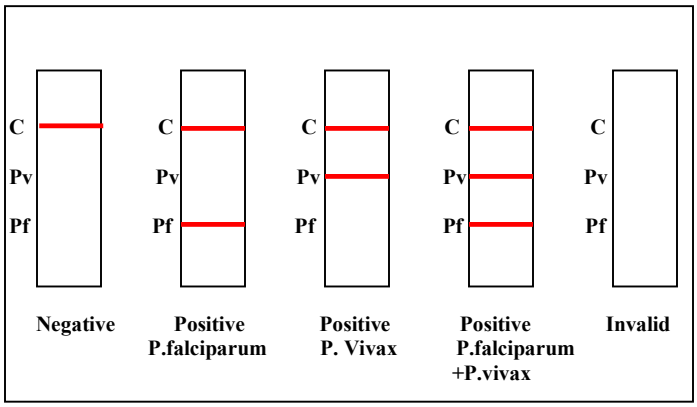
### INTERPRETATION OF RESULTS




**1. Negative reaction**
The presence of only one band (C) within the result window indicates a negative result.

**2. P. falciparum Positive**
The presence of two-color bands (C and Pf) indicates a positive result for P. falciparum.

**3. P. Vivax Positive**
The presence of two-color bands (C and Pv) indicates a positive result for P. vivax.

**4. P. falciparum and other P. Vivax Positive**
The presence of 3 colored bands (C, Pf and Pv) indicate a positive result for P. falciparum and P Vivax.

**5. Invalid**
The test is invalid if the C line does not appear, irrespective of any other test lines appearing or not. 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.

| | Pf | Pv |
|---|---|---|
| Sensitivity | 100 % | 100 % |
| Specificity | 99.8 % | |

**Note: The Malaria Pf/Pv Antigen has sensitivity of 200 parasites/µl of whole blood at base line.**

### BIBLIOGRAPHY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### GLOSSARY OF SYMBOL

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


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