

# MALARIA Pf/Pv Ag RAPID TEST (Whole Blood)

## CLINICAL SIGNIFICATION

Malaria is a serious parasitic disease characterized by fever, chills, 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. Malaria. 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 Pv specific to plasmodium lactate dehydrogenase (pLDH) of plasmodium species (plasmodium 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 plasmodium lactate dehydrogenase (pLDH).

## REAGENTS AND MATERIALS PROVIDED

Malaria Pf/pv Ag Test cards contain the following:

- Test Device with activated silica gel
- Plastic Dropper.
- Assay Buffer Bottle
- Package Insert (Instruction for use)

## MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Alcohol swab
- Lancet
- Specimen collection container Tube

## WARNINGS AND PRECAUTIONS:

### For in Vitro Diagnostic Use

- This package insert must be read completely before performing the test.
- The test device should remain in the sealed pouch until use
- Do not use expired devices.
- Do not use the kit if the cassette package is damaged or the seal is broken.
- Bring all reagent to room temperature (15-30°C) before use.
- Do not use hemolyzed blood specimens for testing.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after performing the test.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and material used to perform the test as bio-hazardous waste.

**REAGENT PREPARATION AND STORAGE INSTRUCTIONS:** All reagents are ready to use as supplied. Store unused test device unopened at 2-30 °C, ensure that the test device brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature 30°C.

## SPECIMEN COLLECTION, STORAGE AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

**Whole Blood:** Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®). Do not use hemolyzed blood for testing.

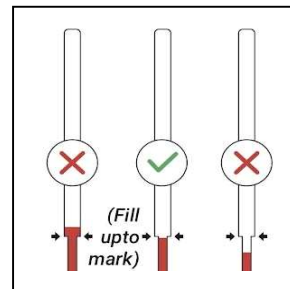
- Whole blood specimens should be stored in refrigeration (2-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

## 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.



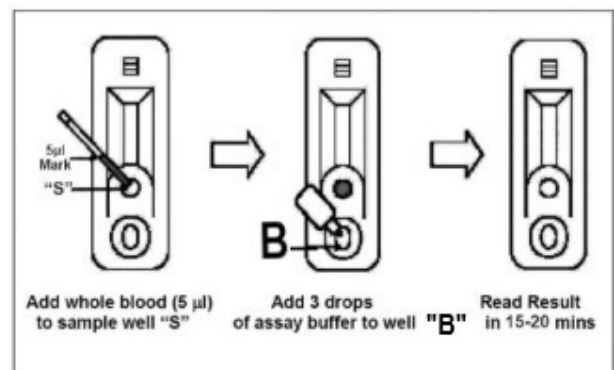
3. Wipe away the first drop of blood with sterile gauze or cotton. Take a sample dropper, and while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the sample dropper up to the mark line.



## DIRECTIONS FOR USE

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it.
2. Remove the test cassette from the sealed pouch and place it on a flat dry surface.
3. Hold the dropper vertically and transfer **5 µl** of whole blood into sample well ("S") (*Do not use excess blood*).
4. Add immediately **3 Drops** of Assay buffer (**approximately 120 µl**), into buffer well ("B"). And start the timer.



5. Wait for the colored line(s) to appear. The test result should be read at 20 minutes.

**Note. Do not interpret the result after 30 minutes.**

## INTERPRETATION OF RESULTS

1. **Negative:** Only one pink-purple band appears in the control window 'C'.



**Negative**

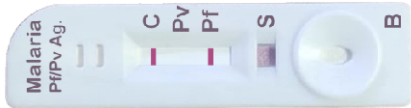
**2. P. falciparum and P. Vivax Positive reaction :**

In addition to the control band, two pink-purple bands also appear under the test region marked 'Pf' and 'Pv'.



**Pf/Pv Positive**

**3. P. falciparum Positive reaction:** In addition to the control band, a pink-purple band also appears under the test region marked 'Pf'.



**Pf Positive**

**4. P. Vivax Positive reaction:** In addition to the control band, a pink-purple band also appears under the test region marked 'Pv'.



**Pv Positive**

**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.



**Invalid**

**PERFORMANCE CHARACTERISTICS**

**1. Clinical Performance For Malaria Pf Ag Test**

A Total of 50 Pf positive sample diagnosed by microscopic examination and 200 non-malaria samples were tested by the Malaria Pf/Pv Ag Rapid Test. Comparison for all subjects is showed in the following table.

Malaria Pf Ag Rapid Test			
Clinic	Positive	Negative	Total
Pf Positive	50	0	50
Negative	4	196	200
Total	54	196	250

**Relative Sensitivity:** 100.0%

**Relative Specificity :** 98.0%

**2. Clinical Performance For Malaria Pv Ag Test**

A Total of 50 Pv positive sample diagnosed by microscopic examination and 200 non-malaria samples were tested by the Malaria Pf/Pv Ag Rapid Test. Comparison for all subjects is showed in the following table.

Malaria Pv Ag Rapid Test			
Clinic	Positive	Negative	Total
Pv Positive	50	0	50
Negative	4	196	200
Total	54	196	250

**Relative Sensitivity:** 100.0%

**Relative Specificity :** 98.0%

**LIMITATIONS**

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. Anti-coagulants. heparin, EDTA, and citrate do not affect the test result.
3. This test kit detects Plasmodium lactate dehydrogenase in patient whole blood and is useful as a screening procedure for malaria diagnosis.
4. Do not mix reagent of different lots.
5. The test is limited to the detection of antigen of Malaria Plasmodium falciparum. 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.

**LIMITED EXPRESS WARRANTY DISCLAIMER**

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**REFERENCE**

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