One Step Malaria Pf/Pv Antigen Test Cassette
Instruction Leaflet

Cat No. MAL 421

INTENDED USE

Malaria *P.f./P.v.* Test Kit is a rapid and convenient immunochromatographic *in vitro* assay. It is used for detection of *Plasmodium falciparum* specific histidine-rich protein II (Pf HRP-II) and *Plasmodium vivax* plasmodium lactate dehydrogenase (pLDH) in whole blood. The test provides a visual, qualitative result, and all positive specimens must be confirmed with other qualified assays. The test is intended for professional use.

SUMMARY

Malaria is one of the world's most prevalent parasitic diseases caused by the *Plasmodium* genus. Four species of *Plasmodium* protozoa cause malaria: *Plasmodium falciparum, P. vivax, P. ovale and P. malaria*. The most serious forms of the disease are caused by *Plasmodium falciparum*. Malaria caused by *P. vivax, P. ovale and P. malaria* causes milder disease in humans that is not generally fatal. Malaria is transmitted usually by the Anopheles mosquito, and malaria infections may also occur from contacting infected blood, such as from blood transfusions. In humans, the parasites migrate to the liver where they mature and release another form, the merozoites, which multiply within red blood cells causing symptoms including fever, chills, flu-like illness and anemia, and in severe cases, coma and death.

PRINCIPLE OF THE ASSAY

The test is an antigen-capture assay detecting presence of two specific soluble proteins Pf HRP-II and pLDH which is present in, and released from, infected red blood cells. The Malaria *P.f./P.v.* Test Kit is based on the capture of parasite antigen from peripheral blood using monoclonal antibodies prepared against a malaria antigen target and conjugated to gold particles in a mobile phase. A second capture monoclonal antibody applied to a strip of nitrocellulose acts as the immobile phase. When the sample is added, it migrates by capillary diffusion trough the strip rehydrating the gold conjugate. If either or both antigens are present, they will bind with the gold conjugated antibodies forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by their corresponding antibodies immobilized there and a visible red line appears. If there are no antigens in the sample, no red line will appear in the Test Zone (T). The gold conjugate will continue to migrate alone until it is captured in the Control Zone (C) from the immobilized goat, anti-mouse IgG antibody and aggregating in a red line, which indicates the validity of the test.

PACKAGE CONTENTS

- Test cassette
- Desiccant
- Lysing solution: 25 tests per bottle
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection capillary tube
- Lancet
- Sterile wipe
- Clock or timer

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.
- Do not use after the expiration date shown on the pouch.
- Handle all specimens as though they contain infectious agents.
- Dispose all specimens and used devices in a proper biohazard container.
- Keep out of children's reach.

SPECIMEN PREPARATION

- Handle all samples with care as they are all capable of transmitting infectious diseases. Dispose all materials that come in contact with the specimen as infectious waste.
- Sample should be collected aseptically by a fingerstick or venipuncture according to standard methods.
- Whole blood samples should be used immediately.
- Use a collection capillary tube to deliver 5 µl samples or collect venous blood into EDTA tube. Use a lancet to puncture the skin and allow a blood droplet to form. Touch the collection capillary tube to the blood droplet and transfer to the test strip immediately. To collect venous blood, use the standard venipuncture procedure and collect blood into an EDTA tube.
- If the test cannot be performed immediately, the blood may be stored for up to three days at 2ºC to 8ºC. Ensure that the blood sample warms to room temperature prior to use.

TEST PROCEDURES

1. Remove the testing device from the sealed pouch by tearing at the notch. Then place the testing device on a leveled surface.

2. Using a sterile lancet and clean specimen collection capillary tube, collect blood by puncturing an accessible site. Allow a blood droplet to form at the puncture site and touch the tip of the capillary tube to the blood droplet. About 5 µl blood may be used.

3. Transfer the blood sample from the capillary tube to the upper well (A) of test device by holding the capillary vertically and gently touching the end against the pad within the sample addition port until all of the blood has been transferred **or** use a pipette to add 5 µl of blood into the sample well.

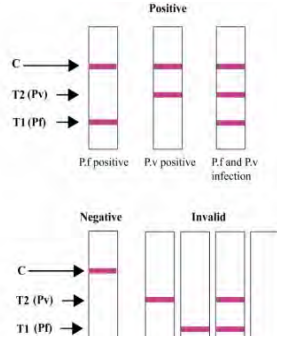
4. Immediately add four （4） drops of the assay diluent to the bottom well (B) of the testing device.

5. Read the result in 20-40 minutes.

DO NOT INTERPRET RESULTS AFTER 40 MINUTES

RESULT INTERPRETATIONS

(Please refer to the illustration)



Negative
A pink colored band appears only at the control region.

Positive
***P.v.* positive:**
Colour bands appear at the control and test region 2.
***P.f.* positive:**
Color bands appear at control region (C) and P.f (T1) test regions.
***P.f./P.v.* positive:**
Colour bands appear at the control and test regions 1 and 2.

Invalid
No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

The testing device contains an internal quality control (pink colored band in the control region). Good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is designed for *in vitro* diagnostic use only.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The performance of our Malaria *P.f./P.v.* Test Kit in comparison with microscopic examination:

Microscopic examination	Malaria *P.f./P.v.* Test Kit		Total
	+	-	
+	323	1	324
-	1	249	250
Total	324	250	574

Sensitivity: 323/324 = 99.7%
Specificity: 249/250 = 99.6%
Agreement: (323+249)/574 = 99.7%
The results show that the test is very accurate to microscopic examination with general agreement of 99.7% in *P.f./P.v.* specimens

Detection of *Plasmodium falciparum* and *Plasmodium vivax*

Malaria Ag *P.f./P.v.* Test for the detection of *P. falciparum* and *P. vivax* malaria according to the level of parasite is presented below.

Parasites per µl	Microscopy (no. of positive)	Malaria *P.f./P.v.*	Sensitivity (%)
>5000	52	52	100%
1000-5000	67	67	100%
500-1000	76	76	100%
200-500	83	83	100%
100-200	34	34	100%
1-100	12	11	91.7%
Overall	324	323	99.7%

Precision

Within-run and between-run have been determined by testing 10 replicates of four specimens: a negative, a low positive, a medium positive and a strong positive. All values were correctly identified 100% of the time.

To evaluate the interference of Malaria Ag *P.f./P.v.* Test kit with known relevant interfering specimens, the haemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples wereinvestigated. In these studies, those specimens did not interfere with the Malaria Ag *P.f./P.v.* Test.

Assay for the detection of Malaria according to the level of parasite.
**Plasmodium falciparum*: Sensitivity with > 200 parasite/µl of blood is 100%.
**Plasmodium vivax:* Sensitivity with > 200 parasite/µl of blood is 100%.

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