HOMEMED MALARIA (P.f/P.v)
ANTIGEN RAPID TEST DEVICE

HOMEMED

For in vitro diagnostic use by healthcare professionals only.

INTENDED USE

The HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection and differentiation of circulating antigens of *Plasmodium falciparum* (P.f) and/or *Plasmodium vivax* (P.v) in human whole blood. This test is a **SCREENING** test only. All positive results should be confirmed. For healthcare professional use only.

BACKGROUND

Malaria is caused by a protozoan which invades human red blood cells.[1] The World Health Organization figures of 2006 estimated that 3.3 billion people were at risk of acquiring malaria, with 247 million of these developing clinical malaria (86% in Africa) and nearly 1 million (mostly African children) dying from the disease.[2] Microscopic analysis of appropriately stained thick and thin blood smears has been the standard diagnostic technique for identifying malaria infections for more than a century.[3] The technique is capable of accurate and reliable diagnosis when performed by skilled microscopists using defined protocols. The skill of the microscopist and use of proven and defined procedures, frequently present the greatest obstacles to fully achieving the potential accuracy of microscopic diagnosis. Although there is a logistical burden associated with performing a time-intensive, labour-intensive and equipment-intensive procedure such as diagnostic microscopy, it is the training required to establish and sustain competent performance of microscopy that poses the greatest difficulty in employing this diagnostic technology. The HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device is a rapid test to qualitatively detect the presence of *P. falciparum*-specific HRP-II antigens and/or *P. vivax* LDH antigens found in *P. vivax, in human whole blood.* The test utilises a colloidal gold conjugate to selectively detect *P.f*-specific and *P.v*-specific antigens in whole blood.

PRINCIPLE

The HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device is a qualitative, membrane based immunoassay for the detection of P. falciparum and/or *P. vivax* antigens in human whole blood. The membrane is pre-coated with anti-*P.f* HRP-II antibodies and anti-*P.v* LDH antibodies. During testing, the whole blood specimen reacts with the dye conjugate, which has been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action, reacts with anti-*P.f* HRP-II antibodies on the membrane at the *P.f* test line region (P.f) and with anti-*P.v* LDH antibodies on the membrane at the *P.v* test line region (P.v). If the specimen contains HRP-II, or *P.v* LDH or both, a coloured line will form in the *P.f.* test line region. Or the *P.v* test region or two coloured lines will appear (*P.f* on *P.v* test line region). The absence of the coloured lines in the *P.f* line region or *P.v* line region indicates that the specimen does not contain *P. falciparum* HRP-II and/or *P. vivax* LDH. The appearance of a coloured line at the control line region serves as a procedural control, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

The small pouch contains	The large pouch contains
1 Malaria Test Device	1 Buffer
	1 Disposable pipette
	1 Sterile safety lancet
	1 Alcohol swab

PRECAUTIONS

For *in vitro* diagnostic use only.

- Do not use after expiration date, indicated on the package. Do not use the test if the foil pouch is damaged.
- For use with whole blood specimen only.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens or kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

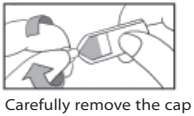
STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expity date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.
- Kits should be kept out of direct sunlight.
- The product is humidity-sensitive and should be used immediately after opened.
- Any test in an improperly sealed pouch should be discarded.
- Containers containing anticoagulants such as EDTA, citrate or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

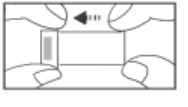
PROCEDURE

IMPORTANT: Test kit, specimen and/or controls should be brought to room temperature (15-30°C) prior to testing. Do not open pouch until ready to perform the test.

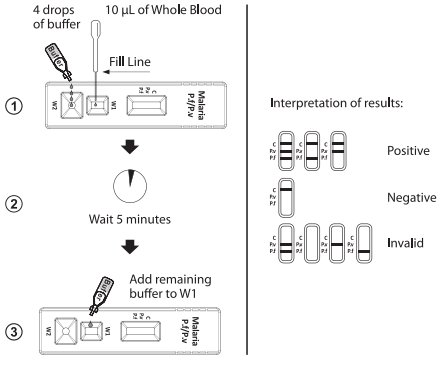
1. Open the small pouch, remove the test device and place it on a clean and level surface.
2. Open the large pouch and remove the buffer ampule, disposable pipette, sterile safety lancet and alcohol swab.
3. Clean the puncture site with the alcohol swab provided.
4. Twist off the cap of the buffer ampule.



5. Carefully remove the cap from the safety lancet. Push the safety lancet firmly against the puncture site until it pricks the finger.



6. Hold the pipette vertically and draw the specimen up to the Fill Line as shown in illustration ① below. Transfer the specimen to the specimen well (W1) of the test device, then add 4 drops of buffer to the diluent well (W2) and start the timer.
7. Avoid trapping air bubbles in the specimen well (W1).
8. **After 5 minutes, add remaining buffer to the specimen well (W1) as shown in illustration ③ below.**
9. Wait for the coloured line(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Refer to the illustration above)

Positive: Two or three coloured lines appear.

***P. falciparum* and *P. vivax* infection:** One line appears in the control line region (C), one line appears in *P.v* test line region (P.v) and another line appears in the *P.f* test line region (P.f).

***P. falciparum* infection:** One line appears in the control line region (C) and another line appears in the *P.f* test line region (P.f).

***P. vivax* infection:** One line appears in the control line region (C) and another line appears in the *P.v* test line region (P.v).

Negative: One coloured line appears in the control line region (C). No line appears in test line region P.f or P.v.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Note:

- The colour intensity of the control- and test lines may vary depending on the concentration of antigens present in the specimen. Any colour change in the test line region should be interpreted as positive, provided a control line is present.
- All positive test results should be confirmed by a laboratory.

QUALITY CONTROL

- Internal procedural controls are included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device is for *in vitro* diagnostic use only. This test should be used for the detection of P.f and/or P.v antibodies in human whole blood. Neither the quantitative value nor the rate of increase in P.f/P.v concentration can be determined by this qualitative test.
2. The HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device will only indicate the presence of antigens of *Plasmodium* sp. (*P.f, P.v*) in the specimen and should not be used as the sole criteria for the diagnosis of malaria infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative test result does not at any time preclude the possibility of malaria infection.
5. This test is intended for screening purposes only.

EXPECTED VALUES

The HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device has been compared with traditional thick or thin microscopic analysis. The correlation between these two systems is > 99.0%.

PERFORMANCE CHARACTERISTICS

Sensitivity: The HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device has been tested with thin or thick microscopy on clinical samples. The results show that the sensitivity of the HOMEMED Malaria P.f/P.v Rapid Test Device is > 99.9% relative to microscopy.

For P.v: Relative Sensitivity: > 99.9% (158/158) (97.6%~100.0%)*

For P.f: Relative Sensitivity: > 99.9% (53/53) (93%~100.0%)*

Specificity: The HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device uses highly specific antibodies for Malaria P.f/Pv antigens in whole blood. The results show that the specificity of the HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device is over 99.0% relative to microscopy.

Relative Specificity: 99.1% (324/327)(97.3%~99.8%)*

Accuracy: 99.4% (535/538)(98.3%~99.8%)*

** 95% Confidence Interval*

Method		MICROSCOPY			Total Results
HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device	Results	Positive		Negative	
		P.v	P.f		
	Positive	0	53	3	56
		158	0	0	158
	Negative	0	0	324	324
Total Results		211		327	538

Precision

Intra-Assay: The run precision has been determined by using 10 replicates of specimens containing negative, low and high positive samples. The negative and positive values were correctly identified > 99% of the time.

Inter-Assay: Between run precision has been determined by using the same specimens of negative, low positive and high positive of 10 independent assays and with three different lots of the HOMEMED Malaria (P.f/P.v) Antigen Rapid Test Device. The negative and positive values were correctly identified >99% of the time.

LITERATURE REFERENCES

1. Bill MaConell, *Malaria Laboratory Diagnosis*. January 2001.
2. WHO, *WHO World Malaria Report 2008.* 2008, WHO – Global Malaria Programme: Geneva.
3. Cooke AH, Chiodini PL, Doherty T, et al, *Comparison of a parasite lactate dehydrogenase-base immunochromatographic antigen detection assay with microscopy for the detection of malaria parasite in human blood samples.* Am J Trop Med Hyp,1999, Feb: 60(2):173-2.

GLOSSARY OF SYMBOLS

	Catalog number	2°C 30°C	Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

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