Malaria P.f. Rapid Test Cassette (Whole Blood)
Package Insert

REF IMA-402 | English

A rapid test for the qualitative detection of circulating plasmodium falciparum (P.f.) in whole blood.

For professional in vitro diagnostic use only

【INTENDED USE】

The Malaria P.f. Rapid Test Cassette (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of circulating plasmodium falciparum in whole blood.

【SUMMARY】

Malaria is caused by a protozoan which invades human red blood cells.[1] Malaria is one of the world's most prevalent diseases. According to the WHO, the worldwide prevalence of the disease is estimated to be 300-500 million cases and over 1 million deaths each year. Most of these victims are infants, young children. Over half of the world's population lives in malarious areas. 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.[2] 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, labor-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 Malaria P.f. Rapid Test Cassette (Whole Blood) is a rapid test to qualitatively detect the presence of the P.f. antigen. The test utilizes colloid gold conjugate to selectively detect P.f. antigen in whole blood.

【PRINCIPLE】

The Malaria P.f. Rapid Test Cassette (Whole Blood) is a qualitative, membrane based immunoassay for the detection of P.f. antigen in whole blood. The membrane is precoated with P.f. antibody. During testing, the whole blood specimen reacts with the dye conjugate, which has been pre-coated in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with P.f. antibody on the membrane on the test line. If the specimen contains P.f. antigen, a colored line will appear in the test region. The absence of the colored line in test region indicates that the specimen does not contain P.f. antigen. To serve as a procedure control, a colored line will always appear in the control region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test cassette contains anti-HRP-II of Plasmodium falciparum antibodies conjugated gold and anti-HRP-II antibodies coated on the membrane

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- For whole blood specimen use only. Do not use other specimens.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures 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 assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test Cassette is stable through the expiration date printed on the sealed pouch. The test Cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Malaria P.f. Rapid Test Cassette (Whole Blood) can be performed using whole blood.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials Provided

• Test Cassettes • Disposable specimen droppers • Buffer • Package insert

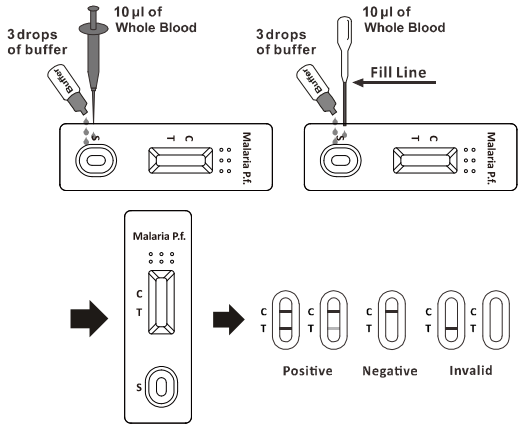
Materials Required But Not Provided

- Pipette and disposable tips (optional)
- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Timer

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening it. Remove the test Cassette from the sealed pouch and use it as soon as possible.
2. Place the Cassette on a clean and level surface.
   For Whole Blood specimen:
   - Use a pipette: To transfer 10μL of whole blood to the specimen well, then add 3 drops of buffer (approximately 180μL), and start the timer.
   - Use a disposal specimen dropper: Hold the dropper vertically; draw the specimen up to the Fill Line as shown in illustration below (approximately 10μL). Transfer the specimen to the specimen well, then add 3 drops of buffer (approximately 180μL), and start the timer.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after **20 minutes.**



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of antigen, vis.,HRP-II present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, 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】

1. The Malaria P.f. Rapid Test Cassette (Whole Blood) is for in vitro diagnostic use only. This test should be used for the detection of P.f. antigen in whole blood specimens only. Neither the quantitative value nor the rate of increase in P.f. antigen concentration can be determined by this qualitative test.
2. The Malaria P.f. Rapid Test Cassette (Whole Blood) will only indicate the presence of P.f. antigen 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 result does not at any time preclude the possibility of malaria infection.

【EXPECTED VALUES】

The Malaria P.f. Rapid Test Cassette (Whole Blood) has been compared with traditional thick or thin blood smears microscopic analysis. The correlation between the two systems is > 99%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Malaria P.f. Rapid Test Cassette (Whole Blood) uses an antibody that is highly specific for Malaria P.f. antigen in whole blood. The Malaria P.f. Rapid Test Cassette (Whole Blood) has been tested with thin or thick blood smears on clinical samples. The results show that the sensitivity of the Malaria P.f. Rapid Test Cassette (Whole Blood) is over 99.0% relative to blood smears.And the results show that the specificity of the Malaria P.f. Rapid Test Cassette (Whole Blood) is > 99% relative to blood smears.

Method		Blood Smears Microscopy		Total Result
Malaria P.f. Rapid Test Cassette(Whole Blood)	Results	Positive	Negative	
	Positive	90	0	90
	Negative	0	467	467
Total Result		90	467	557

Relative sensitivity: >99.9% (95%CI*: 96.7%~100.0%);
Relative specificity: >99.9% (95%CI*: 99.4%~100.0%);
Accuracy: >99.9% (95%CI*: 99.5%~100.0%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: negative, low titer positive and high titer positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: negative, low titer positive and high titer positive specimens. Three different lots of the Malaria P.f. Rapid Test Cassette (Whole Blood) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Malaria P.f. Rapid Test Cassette (Whole Blood) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, HCV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Malaria negative and positive specimens.

Acetaminophen: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL
Creatin: 200 mg/dL
Oxalic Acid: 60mg/dL
Caffeine: 20 mg/dL
Gentisic Acid: 20 mg/dL
Albumin: 2 g/dL
Bilirubin: 1g/dL

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. Bill MaConell, Malaria Laboratory Diagnosis. January 2001
2. 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

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only	⌛	Use by	⊘	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Hangzhou AllTest Biotech Co., Ltd.
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