Malaria P.f. Device (2-30°C)

CE

CATALOGUE NUMBER	KIT SIZE
RADMAL2	20 Tests

Intended Use:
The Malaria plasmodium falciparum (P.f.) Rapid Test Strip (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of circulating antigens of *Plasmodium falciparum* in whole blood.

Introduction:
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 Device (Whole Blood) is a rapid test to qualitatively detect the presence of the P.f. antigen.

Test Principle:
The Malaria P.f. Rapid Test Device (Whole Blood) is a qualitative, membrane based immunoassay for the detection of P.f. antigen in whole blood. The membrane is pre-coated with P.f. antibody. During testing, the whole blood specimen reacts with the dye conjugate, which has been pre-coated in the test strip. 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 device contains monoclonal anti-P.-falciparum antibodies coated on the membrane.

Materials Provided:
Individually pouched test devices
Disposable specimen pipettes
Buffer
Package Insert

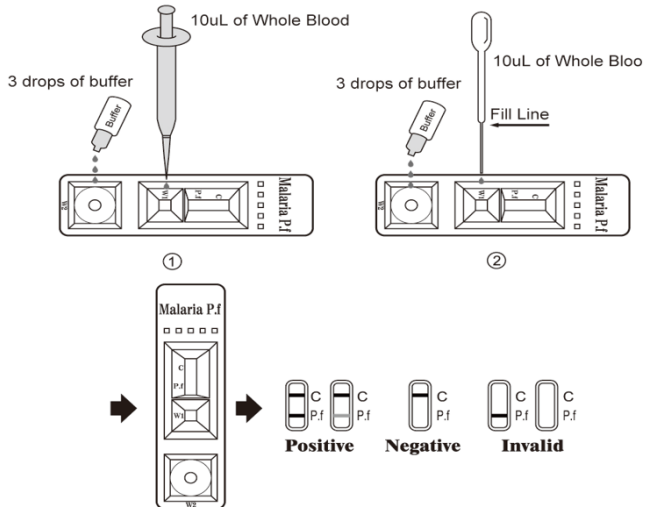
Materials not provided: Timer, Specimen collection container, Pipette and disposable tips (optional), Lancest (for fingerstick whole blood only)

Precautions:
- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- For use with whole blood specimen 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.

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

Specimen Collection and Storage:
- The Malaria P.f. Rapid Test Device (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.

Assay Procedure:
Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Transfer the specimen by a pipette or a dropper:
   - To use a **Pipette:** Transfer 10 µL of whole blood to the specimen well (S) of the test device, then add 3 full drops of buffer (approximately 120 µL) and start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration ① below.
   - To use a **Disposable Specimen Dropper**: Hold the dropper vertically, draw the specimen up to the Fill Line as shown in illustration ② below (approximately 10µL). Transfer the specimen to the specimen well (S) of the test device, then add 3 full drops of buffer (approximately 120 uL) and start the timer. Avoid trapping air bubbles in the specimen well (S)
3. Wait for the red line(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.



Interpretation of results:
(Please refer to the illustration above)
POSITIVE:* Two distinct colored lines appear. One line should be in the control region (C) and another line should be in the test region (T).
NEGATIVE: Only one colored line appears in the control region.
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 strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Quality Controls:
Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal 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 of the Test:
1. The Malaria P.f. Rapid Test Device (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 Device (Whole Blood) will only indicate the presence of P.f. antigen 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 result does not at any time preclude the possibility of malaria infection.

Expected Value:
The Malaria P.f. Rapid Test Device (Whole Blood) has been compared with traditional thick or thin blood smears microscopic analysis. The correlation between the two systems is >99.0%.

Performance Characteristics:

Sensitivity
The Malaria P.f. Rapid Test Device (Whole Blood) has been tested with thin or thick blood smears on clinical specimens. The results show that the sensitivity of The Malaria P.f. Rapid Test Device (Whole Blood) is >99.0% relative to blood smears.

Specificity
The Malaria P.f. Rapid Test Device (Whole Blood) uses an antibody that is highly specific for Malaria P.f. antigen in whole blood. The results show that the specificity of The Malaria P.f. Rapid Test Device (Whole Blood) is >99.0% relative to blood smears.

AMS U.K Ltd., 42, Ballymena Business Centre, Galgorm, Co.Antrim, BT42 1FL. Tel: +44(0)28 25656268
www.amslabs.co.uk info@amslabs.co.uk

V1: rev Apr 2015

* 95% Confidence Interval

Method		Microscopy		Total Results
Malaria P.f. Rapid Test Strip	Results	Positive	Negative	
	Positive	53	3	56
	Negative	0	324	324
Total Results		53	327	380

Note: Relative Sensitivity: >99.9% (93.0%-100.0%)* Relative Specificity: >99.1% (97.3%-99.8%)*
Accuracy: >99.0% (99.0%-100.0%)* * 95% Confidence Interval

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 Malaria P.f Rapid Test Device(Whole Blood). The negative and positive values were correctly identified >99% of the time.

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

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

AMS U.K Ltd., 42, Ballymena Business Centre, Galgorm, Co.Antrim, BT42 1FL. Tel: +44(0)28 25656268
www.amslabs.co.uk info@amslabs.co.uk