Malaria Plasmodium Falciparum Rapid Test

Cat.No: DTSXY-L6

Lot. No. (See product label)

Intended Use

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

General Description

Malaria is caused by a protozoan which invades human red blood cells.1Malaria is one of the world's most prevalent diseases. According to the WHO, the worldwide prevalence of the disease is estimated to be300-500 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.2The 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.

Principle Of The Test

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 precoated with P.f. antibody. During testing, the whole blood specimen reacts with the dye conjugate, which has been pre-coated in the Test Device. 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 And Materials Provided

The Test Device contains monoclonal anti-P.falciparumantibodies coated on the membrane

- Test Devices
- Disposable specimen droppers
- Buffer
- Package insert

Materials Required But Not Supplied

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

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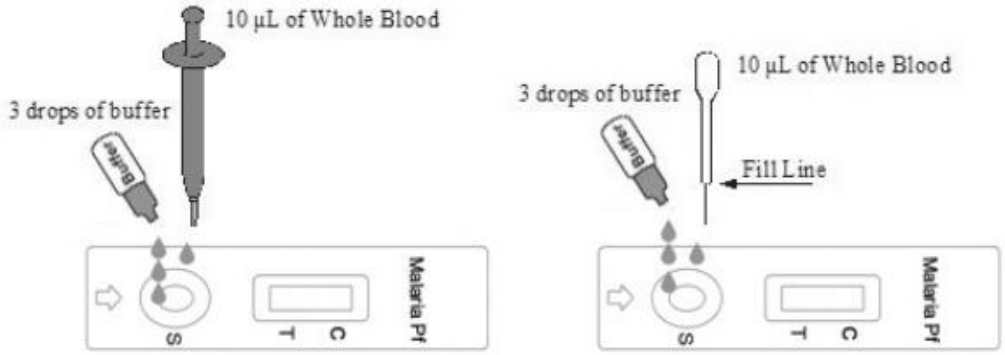
Specimen Collection And Preparation

• 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.

Reconstitution And Storage

The kit can be stored at room temperature or refrigerated (2-30°C). The Test Device 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.

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. Transfer the specimen to the specimentube by a pipette or a dropper:
• To use a **Pipette:** Transfer 10 µL of whole blood to the specimen well (S), then **add 3 drops of buffer** (approximately 120 µL), and start the timer.
• To use a **Disposable 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 (S), then **add 3 drops of buffer** (approximately 120 µL), and start the timer

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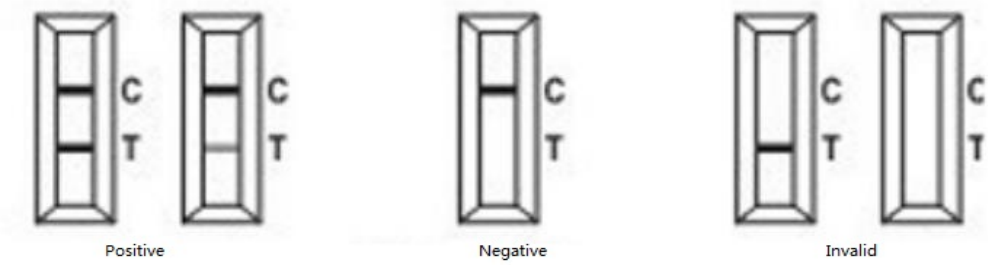
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive 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.

Interpretation Of Results



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).
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of P.f. present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test 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 Device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Reference Values

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 99.7%.

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 99.7% relative to blood smears.

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Method		Blood Smears		Total Results
Malaria P.f. Rapid Test Device	Results	Positive	Negative	
	Positive	43	1	44
	Negative	0	323	323
Total Results		43	324	367

Relative Sensitivity: >99.0% (91.8%-100.0%)* Relative Specificity: 99.7% (98.3%-100.0%)* Accuracy: 99.7% (98.5%-100.0%)*
* 95% Confidence Interval

Precision

Intra Assay

Within-run precision has been determined by using 10 replicates of twelve specimens containing negative, low positive 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 twelve 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.

Precautions

- 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.

Limitations

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.

References

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

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