

One Step Rapid Malaria P.f & P. v. Test

Malaria P.f.&P.V. (Whole Blood)

INTENDED USE

The Malaria (P.f&Pv).Rapid Test Device (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of circulating plasmodium falciparum and Plasmodium vivax in whole blood .The Device include P.v.Test (left) and P.f.Test (right)

PRINCIPLE

The Malaria Rapid Test Device (Whole Blood) is a qualitative, membrane based immunoassay for the detection of Malaria (P.f&P.V). antigen in whole blood. The membrane is pre-coated with Malaria 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 Malaria antibody on the membrane on the test line. If the specimen contains Malaria antigen, a red line will appear in the test region. The absence of the red line in test region indicates that the specimen does not contain Malaria antigen. To serve as a procedural control, a red 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 Malaria antibody 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.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The Device 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.

SPECIMEN COLLECTION AND PREPARATION

- The Malaria 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. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

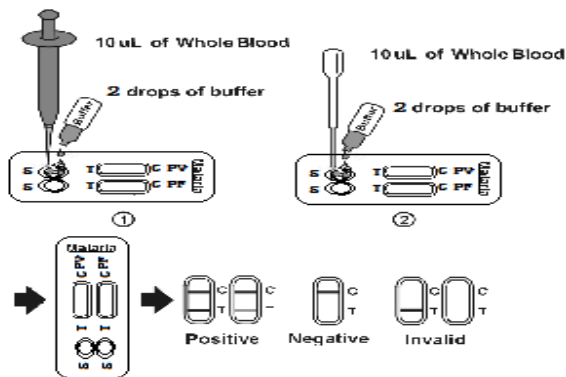
- Materials Provided
- Test devices
- Disposable specimen droppers
- Buffer
- Package insert
- Materials Required But Not Provided
- Pipette and disposable tips (optional)
- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Timer

DIRECTIONS FOR USE

Bring 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 uL of whole blood to the specimen well (S) of the test device, then add 2 full drops of buffer (approximately 60uL) 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 10 uL). Transfer the specimen to the specimen well (S) of the test device, then add 2 full drops of buffer (approximately 60uL) 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.



POSITIVE: * **Two distinct red 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 red color in the test line region (T) may vary depending on the concentration of Malaria present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: **One red line appears in the control region (C).** No apparent red or pink 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.

BIBLIOGRAPHY

1. Bill McConell, 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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