Malaria Plasmodium Falciparum Rapid Test Kit

(Immunochromatography)

Product Name

Malaria Plasmodium Falciparum (P.f.) Rapid Test Kit (Immunochromatography)

Intended Use

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

Test Principle

The Malaria P.f. Rapid Test Kit is designed for the qualitative detection of P.f. antigen in whole blood. The membrane is pre-coated with P.f. antibody. During testing, the whole blood sample 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 to form the T line. If the sample 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 sample 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 sample has been added and membrane wicking has occurred.

Main Components

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent pad, PVC board

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Sample Requirement

1. A sample must be collected in a clean and dry container. Detect immediately after collecting blood.

2. Use fresh samples. Samples may be stored at 2-8℃ for 3 days prior to assay, and store at -20 ℃ if cannot be used immediately.

Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Strip and Cassette:

1. Take off the outer packing, put the strip/cassette onto the desk with the sample adding area of the strip/ sample hole of the cassette up.

2. Drop 5μL of whole blood vertically into the sample adding area of the strip /sample hole of the cassette. Add 4 drops(160μL-200μL) of sample buffer into the sample adding area of the strip / sample hole of the cassette.

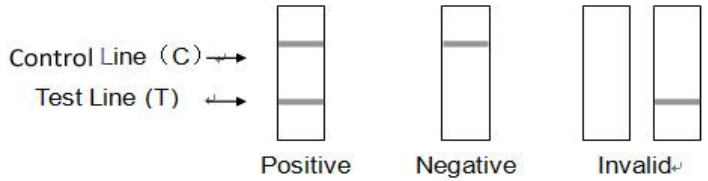
3. Observe the test results immediately within 15 minutes, the result is invalid over 20 minutes.

Result Judgment

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

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

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



Limitation

1. For IN VITRO diagnostic use 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 Kit will only indicate the presence of P.f. antigen in the sample 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 preclude the possibility of malaria infection.

5. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.

Precaution

1. For IN VITRO diagnose only.

2. Do not use after the expiration date.

3. The test result is invalid over 20 minutes.

4. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

5. If the sample is too thick, the climb speed is less than 4mm/min on the description page, false positive

may occur. Other methods are suggested.