Malaria P.Falciparum/P.Vivax Rapid Test Cassette

(Immunochromatography)

Product Name

Malaria P.Falciparum/P.Vivax Rapid Test Cassette (Immunochromatography)

Intended Use

The Malaria P.f/Pv Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of circulating antigens of *Plasmodium falciparum, Plasmodium vivax* in whole blood.

Test Principle

The Malaria P.f/P.v Rapid Test Cassette is designed for the qualitative detection of *P.f and P.v* antigen in whole blood. The membrane is pre-coated with *P.f and P.v* 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 and P.v* antibody to form the T line. If the sample contains *P.f and P.v* 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 and P.v*. 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 paper and 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. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants.

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℃)

Cassette:

1. Take off the outer packing, put the cassette onto the desk with the sample window up.

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

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

Result Judgment

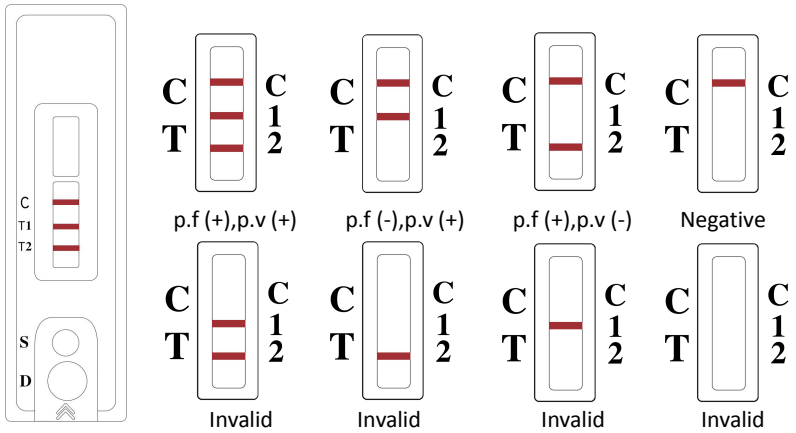
POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T1 test region (T1), indicating the P.v. infection.

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T2 test region (T2), indicating the P.f. infection.

POSITIVE: Three distinct red lines appear in the control region (C), the T1 test region (T1) and the T2 test region (T2), indicating the P.v. and P.f. infection.

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T1 and T2).

INVALID: No red bands appear or control line fails to appear, indicating that the operator error or reagent failure.



Limitation

1. For human whole blood only. The blood should be used in 1 hour after collection.

2. This reagent is designed for the qualitative screening test. Concentration of P.f. and P.v. cannot be determined by this qualitative test.

3. Wrong operation can result in abnormal results. Please test again if the result is suspicious.

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.

6. A hook effect may occur when the density of P.f. or P.v is too high in the sample. Samples should be properly diluted for the right test result.

7. 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.