

Rapid Malaria pf-HRP-2 Antigen Test

A rapid test for the qualitative detection of Malaria falciparum antigen in human blood sample

Catalog Number: 1Q06C2

For In Vitro Diagnostic Use Only

INTENDED USE

For the rapid qualitative detection of P. falciparum specific histidine rich protein-2 (Pf HRP-2) in human blood. blood samples. This test is an aid in the diagnosis of Malaria falciparum (pf) infection.

SUMMARY

Malaria is a serious parasitic disease characterized by fever, chills, and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds of malaria that can infect humans: *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale*, and *Plasmodium malariae*. Of these, p. falciparum is the most prevalent and severe species that is responsible for most of the morbidity and mortality worldwide. Early detection of p. falciparum malaria is of paramount importance due to the incidence of cerebral malaria and the associated drug resistance. Pf HRP-2 is a water-soluble protein that is released from parasitised erythrocytes of infected individuals and is specific to the p. falciparum species.

TEST PRINCIPLE

The Rapid Malaria pf-HRP2 Antigen Test contains a membrane strip, which is pre-coated with anti-pf HRP2 monoclonal antibodies on the test line region of the strip. When a Whole Blood specimen is applied at one end of the membrane and following the application of the assay buffer, it reacts with the colloidal gold-anti-pf HRP2 antibody that have already been applied to the specimen pad. The mixture then migrates chromatographically towards the other end of the membrane and reacts with the monoclonal antibodies previously placed on the test line region. If the blood contains HRP2 antigen, a colored line will appear in the test line region, showing a positive result. The absence of the colored line in the test region indicates a negative result. It suggests the blood sample does not contain detectable levels of malaria p. falciparum parasites. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly. This control line serves to validate the performance of the test.

MATERIALS PROVIDED

1. Rapid Malaria pf-HRP2 Antigen Test Device
2. Assay Buffer
3. Instructions for Use

Materials Not Provided:

1. Calibrated pipette
2. Lancet
3. Timer

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (4-30°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.

PRECAUTIONS

For professional *in vitro* diagnostic use only. Do not use after expiration date.

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 testing 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 being tested.

SPECIMEN COLLECTION & PREPARATION

[Collection by venipuncture]

- 1) Collect whole blood into a collection tube (containing EDTA, citrate or heparin) by venipuncture.
- 2) If specimens are not immediately tested, they should be refrigerated at 2 ~ 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen after long-term storage of more than three days can cause non-specific reaction.
- 3) When stored at 4 ~ 8°C, the whole blood sample should be used within three days.

[Collection using a lancet]

- 1) Clean the area to be lanced with an alcohol swab.
- 2) Squeeze the end of the fingertip and pierce with a sterile lancet provided.
- 3) Wipe away the first drop of blood with sterile gauze or cotton.
- 4) Using a 5 µL calibrated dropper tube, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the dropper.

PROCEDURE

Allow test device, buffer, specimen to equilibrate to room temperature (15-30°C) prior to testing.

- 1) Add 5 µl of whole blood into sample well [S1], the small well.
Add two drops (80 µLs) of assay buffer into developer well [S].
- 2) Read the test result in 20 min.

Positive sample may show positive results within a few minutes after the sample is added. However, to confirm a negative result, please wait until 20 minutes.

INTERPRETATION OF RESULTS

1) Positive:

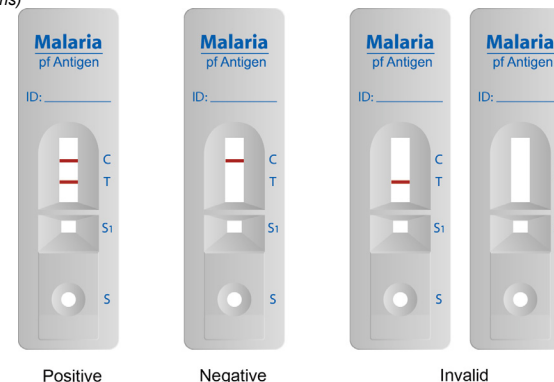
The presence of two color bands indicates a positive result for Malaria.

2) Negative:

The presence of only one band in the control region of the result window indicates a negative result.

3) Invalid :

The test is invalid if the control line does not appear. If this occurs, the test should be repeated using a new device. *(Please refer to the illustrations)*



LIMITATIONS

- 1) The positive result obtained with Rapid Malaria pf-HRP2 Antigen Test alone cannot be the final diagnosis of malaria infection. Any positive result must be interpreted in conjunction with the patient clinical history and other laboratory testing results.
- 2) Negative results do not rule out the possibility of malaria exposure or infection.
- 3) As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

REFERENCES

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