Tell Me Fast Malaria P. falciparum Test Strip (Whole Blood)
Instructions for Use
Catalog Number: B700S

A rapid test for the qualitative detection of P. falciparum specific histidine rich protein-2 (Pf HRP-2) in whole blood samples.

For professional in vitro test use only.

Intended Use

The *TELL ME FAST* Malaria P*. falciparum* Test Strip (Whole Blood) is a rapid, qualitative, membrane-based immunoassay intended for the detection of P. falciparum specific histidine rich protein-2 (Pf HRP-2) in whole blood samples.

Summary

Four species of the plasmodium parasites are responsible for malaria infections in humans. The species are: p. falciparum, p. vivax, p. ovale and p. 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.

Principle

The *TELL ME FAST* Malaria *p. falciparum* Test Strip (Whole Blood) is a qualitative, membrane-based immunoassay for the detection of malaria p. falciparum in whole blood. The membrane is coated with anti Pf HRP-2 antibody 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 clearing buffer, it reacts with anti Pf HRP-2 antibody coated particle that has already been applied to the specimen pad at the same end. The mixture then migrates chromatographically towards the other end of the membrane and reacts with the anti Pf HRP-2 antibody on the membrane in the test line region. If the whole blood contains p. falciparum parasites, a colored line will appear in the test line region, showing a positive result. The absence of the colored line indicates that the whole blood does not contain detectable levels of the p. falciparum *HRP-2*, showing a negative result. 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.

Reagents

The test device contains antibody to *Pf HRP-2* coated particles and antibody to *Pf HRP-2* coated on the membrane.

Precautions

- For professional *in vitro* use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as though they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protectors when specimens are assayed.
- Humidity and temperature can adversely affect results.

Storage & Stability

Store as packaged in the sealed pouch at 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. The buffer should be stored at 2-30 °C. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials Provided:
- Test Device
- Clearing Buffer
- Instructions for Use

Materials Required but not Provided:
- Specimen collection container
- Calibrated micro pipette capable of delivering 5 µl sample accurately
- Lancet
- Timer

Specimen Collection & Preparation

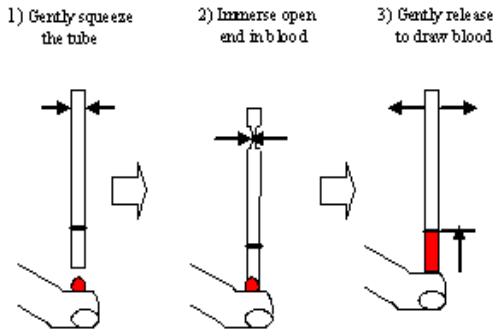
[Collection by venipuncture]

1) Collect the whole blood into the 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 in the long-term keeping more than three days can cause non-specific reaction.
3) When storage at 2 ~ 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) Take a capillary 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.

Directions for Use:



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

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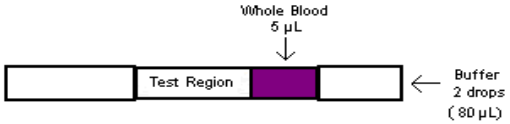
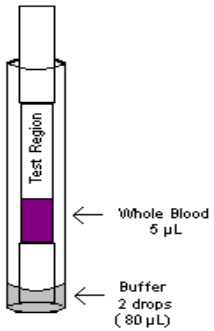
Method 1:

1. Lay the test strip flat on a clean surface.
2. Dispense 5 µl of whole blood onto the gold pad - the purplish part of the strip (see image below).
3. Add 2 drops (80 µl) of buffer onto the bottom of the strip just below the gold pad.
4. Start the timer and interpret the result after 20 minutes.



Method 2:

1. Lay the test strip flat on a clean surface.
2. Dispense 5 µl of whole blood onto the gold pad - the purplish part of the strip (see image below).
3. Add 2 drops (80 µl) of buffer into the bottom of a test tube.
4. Place strip in tube as shown in the diagram. Do not allow buffer to touch gold pad.
5. Start the timer and interpret the result after 20 minutes.



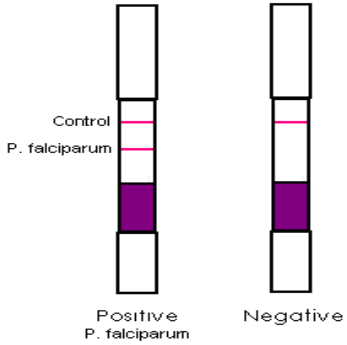
NOTE: Do not interpret the result after 30 minutes.

Interpretation of Results:

(Please refer to illustrations)

***1) P. falciparum* Positive reaction**

The presence of two color bands (c and 1) indicates a positive result for *P. falciparum*. The Pf HRP-2 present in the sample reacts with the Pf HRP-2 conjugate and move through the test strip where the Pf HRP-2 is captured by the anti- P. falciparum specific histidine rich protein-2 (Pf HRP-2).

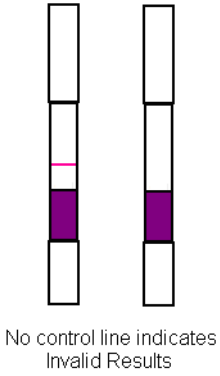


2) Negative reaction

The presence of only one band within 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 strip.



Limitations

1. Since the Pf HRP-2 persists for up to two weeks, even after successful therapy, a positive test result does not indicate a failed therapeutic response.
2. In case the test is used to monitor success of therapy, testing is advised only from 15 days after the completion of therapy.
3. As with all diagnostic tests, the results must always be correlated with clinical findings. The test should not be used as the only criteria for diagnosis.
4. The *TELL ME FAST* Malaria *p. falciparum* Test Device (Whole Blood) is for *in vitro* use only. The test should be used for the detection of Pf HRP-2 in whole blood specimen.
5. If the test result is negative and clinical symptoms persist, additional follow-up tests using other clinical methods are recommended.

Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

Bibliography

1. Howard, RJ, et al. *The secretion of a Malaria Histidine-rich Protein (Pf HRP II) from Plasmodium falciparum-infected Erythrocytes.* J. Cell Biol., (1986)103, 1269-1277
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