**Tell Me Fast™ Malaria**
**P. falciparum Test Device**
**(Whole Blood)**
**Instructions for Use**
**Catalog Number: B700C**

*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

*TELL ME FAST* Malaria *p. falciparum* Test Device (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

*TELL ME FAST* Malaria *p. falciparum* Test Device (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

- The *TELL ME FAST* Malaria *p. falciparum* Test Device (Whole Blood) uses fresh anti coagulated Whole Blood as the sample. Heparin, EDTA or Oxalate can be used as suitable anticoagulants.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days.
- Clotted or contaminated blood samples should not be used to perform the test.
- Fresh blood from finger prick / puncture may also be used as a test specimen
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

## Directions for Use:

**Allow test device, buffer, whole blood specimen 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 5µl of Whole Blood to the sample well [ “S” ] of the device.
3. Then slowly add 2 drops (80µl) of clearing buffer to the sample well. Add the clearing buffer one drop at a time. Start the timer.
4. Wait for the red line(s) to appear. The test line should be read at 20 minutes.

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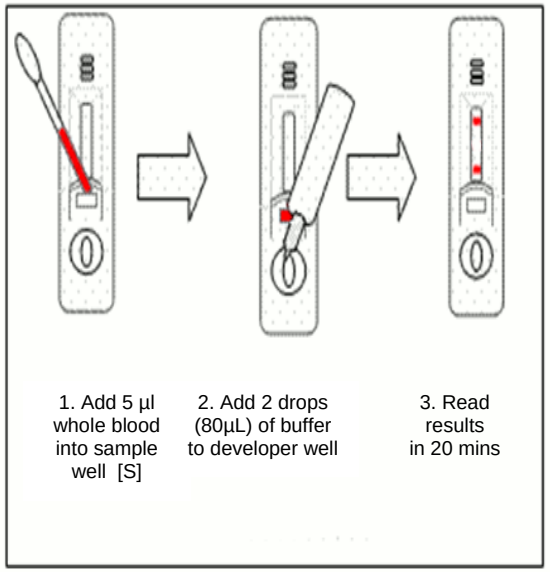


1. Add 5 µl whole blood into sample well [S]
2. Add 2 drops (80µL) of buffer to developer well
3. Read results in 20 mins

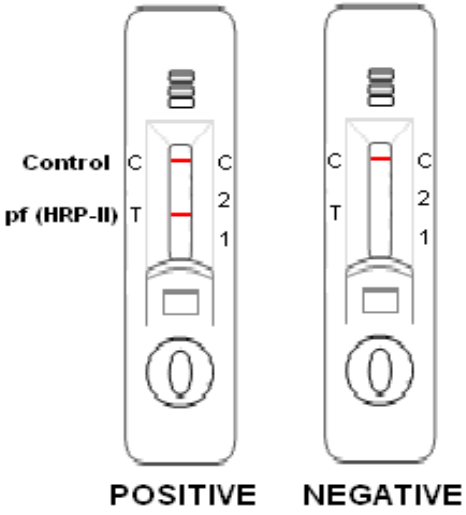
Note: Low titers of Pf HRP-2 in the hemolysed sample might result in a faint line appearing in the test region (T) after a prolonged time. Do not interpret the result after 15 minutes.

## Interpretation of Results:

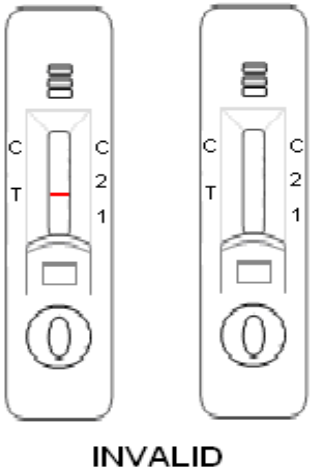
*(Please refer to the illustration)*

**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).

**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 strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.




## Limitations

1. Since the Pf HRP-2 persists for up to a fortnight 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. *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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