

Malaria Pf Rapid Device

A rapid, qualitative, two site sandwich immunoassay for the determination of *P. falciparum* specific histidine rich protein-2 (Pf HRP-2) in whole blood. For professional *in vitro* diagnostic use only.

CAT. NO. PRODUCT DESCRIPTION
8/602 Malaria Pf Rapid Device – 25Tests

INTRODUCTION

Intended Use

Four species of the Plasmodium parasites are responsible for malaria infections in humans: *P. falciparum* (*P.f.*), *P. vivax*, *P. ovale* and *P. malariae*. Of these *P.f.* is the most prevalent and severe species that is responsible for most of the morbidity and mortality worldwide. Early detection of *P.f.* malaria is of paramount importance due to incidence of cerebral malaria and drug resistance associated with it.

Pf HRP-2 is a water-soluble protein that is released from parasitised erythrocytes of infected individuals and is specific to the *P.f.* species. The BIOTEC Malaria Pf Rapid Device detects the presence of Pf HRP-2 in whole blood specimens and is a sensitive and specific test for the detection of *P.f.* malaria.

Principles of the Method

The BIOTEC Malaria Pf Rapid Device is a rapid immunochromatographic test. As the test sample flows through the membrane assembly, after addition of the clearing buffer, the coloured anti Pf HRP-2 colloidal gold conjugate (monoclonal) antisera complexes the Pf HRP-2 in the lysed sample. This complex moves further on the membrane to the test region where it is immobilised by the anti-Pf HRP-2 (monoclonal) antisera coated on the membrane. This leads to formation of a pink coloured band, which confirms a positive test result. Absence of this coloured band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any, move further on the membrane and are subsequently immobilised by anti-rabbit antibodies coated on the membrane at the control region, forming a pink band. This control band serves to validate the test performance.

PRODUCT CONTENTS

Each kit contains:

- 25 Individual pouches, each containing:
 - Test Device: Membrane assembly pre-dispensed with anti-Pf HRP-2 colloidal gold conjugated antisera, rabbit IgG colloidal gold conjugate, anti-Pf HRP-2 antisera and anti-rabbit antisera at the respective regions.
 - Desiccant Pouch.
 - 5µl sample applicator.
- Clearing buffer in a dropper bottle.
- Instructions for use.

ITEMS REQUIRED BUT NOT PROVIDED

- Calibrated micropipette capable of delivering 5µl sample accurately (optional).
- Specimen collection container.
- Timer.

STORAGE AND SHELF LIFE

- Store as packaged in the sealed pouch at 4-40°C.
- The test device is stable until 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 after the expiration date.
- Do not re-use device.

WARNINGS & PRECAUTIONS

- For professional *in vitro* diagnostic use only. NOT FOR MEDICINAL USE.
- Read the instructions carefully before performing the test.
- Do not mix reagents from different lots.
- Handle all specimens as potentially infectious.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Do not use if pouch or devices are damaged or if any lines are visible on the device before contact with the specimen.
- Follow standard bio-safety guidelines for handling and disposal of potentially infective material.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

9. The used test should be discarded according to local regulations.
10. When used according to the instructions this product presents little risk to the user. However, take note of the following product information. Hazard: **Xn** (harmful). **R22** (harmful if swallowed). **S23** (do not breathe spray), **S46** (if swallowed seek medical advice immediately and show the label), **S61** (avoid release to the environment. Refer to safety data sheet).

SPECIMEN PREPARATION

Fresh anti-coagulated whole blood should be used as a test sample and EDTA or Heparin or Oxalate can be used as suitable anticoagulant. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then the specimen may be stored at 2-8°C for up to 72 hours before testing. Clotted or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick / puncture may also be used as a test specimen.

PROCEDURE

1. Bring the kit components to room temperature before testing.
2. If the pouch has been stored at 2-8°C, allow at least 30 minutes for the device to come to room temperature.
3. Open the pouch and remove the device, sample applicator and desiccant. Check the colour of the desiccant. It should be blue. If it has turned colourless or pink, discard the device and use another device. **Once opened, the device must be used immediately.**
4. Tighten the cap of the clearing buffer provided with the kit in a clockwise direction to pierce the dropper bottle nozzle.
5. Evenly mix the anti-coagulated blood sample by gentle swirling. Dip the sample applicator in to the sample. Ensuring a full loop of blood is retrieved, blot the blood so it collects onto the sample pad in the sample well 'A'. (This delivers approximately 5µl of the whole blood specimen).

OR

6. If finger prick blood is being used, touch the sample applicator to the blood on the finger prick, ensuring a full loop of blood is retrieved and immediately blot the specimen on to the sample pad in the sample well 'A'. Care should be taken that the blood sample has not clotted and the transfer to the sample pad is immediate.

OR

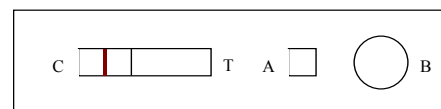
7. Alternatively, 5µl of the anti-coagulated or finger prick specimen may be delivered to the sample pad in the sample well 'A' using a micropipette.

NOTE: Ensure the blood from the sample applicator has been completely taken up by the sample pad.

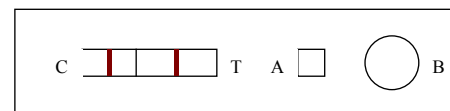
8. Dispense six drops (approx. 300µl) of the clearing buffer into well 'B', by holding the plastic dropper bottle vertically.
9. At the end of 15 minutes, read the results as described below.

INTERPRETATION

Negative for *P. falciparum* malaria: Only one pink coloured band appears in the control window 'C'.



Positive for *P. falciparum* malaria: In addition to the control band, a distinct pink coloured band also appears in the test window 'T'.



The test results should not be interpreted after 15 minutes. The test should be considered invalid if no bands appear on the device or the control line is absent. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

Limitations

1. As with all diagnostic tests, the results must always be correlated with clinical findings.
2. The results of the test are to be interpreted within the epidemiological, clinical and therapeutic context.
3. When it seems indicated, reference parasitological techniques should be considered (microscopic examination of the thick smear and thin blood films).
4. Any modification to the above procedure and/or use of other reagents will invalidate the test procedure.
5. Do not mix devices and buffers of different lots.
6. In *P.f.* infections, HRP-II is not secreted by the gametogeny stage. Hence, in “carriers”, the HRP-2 band may be absent.
7. 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.
8. If the test needs to be used to monitor success of therapy, testing is advised only from 15 days after the completion of therapy.

PERFORMANCE CHARACTERISTICS

1. In an independent study, a panel of 167 samples whose results were earlier confirmed with expert microscopy were tested with the BIOTEC Malaria Pf Rapid Device and the results obtained are as follows:

Sample type	No. samples	Malaria Pf Rapid Device		Sensitivity	Specificity
		Pos.	Neg.		
P.f. pos.	74	73	1	98.6%	-
P.v. pos.	8	0	8	-	100%
Malaria negative	85	1	84	-	98.8%

2. In another independent study, 125 patient samples from a *P.f.* endemic area were tested with the BIOTEC Malaria Pf Rapid Device and microscopy (thick and thin smear). The BIOTEC Malaria Pf Rapid Device was found to be 100% sensitive and 100% specific to *P.f.* against microscopy. All 31 samples that tested positive for *P.f.* under microscopy showed positive results with the BIOTEC Malaria Pf Rapid Device.

The four *P. vivax* positive samples and the 90 malaria negative samples tested negative with the BIOTEC Malaria Pf Rapid Device.

3. In a third independent study, 100 patient samples were tested with the BIOTEC Malaria Pf Rapid Device, with another immunochromatographic test for *P. falciparum* and with microscopy. The BIOTEC Malaria Pf Rapid Device showed a 99% correlation with microscopy and a 98% correlation with the other immunochromatographic test.
4. From the above results and the results of in house data, the BIOTEC Malaria Pf Rapid Device is a highly sensitive and specific test for the diagnosis of *falciparum* malaria.

REFERENCES

1. Howard, R.J., *et al*, 1986: Secretion of a Malarial Histidine-rich Protein (Pf HRP II) from *Plasmodium falciparum*-infected Erythrocytes. *J. Cell Biol.*, 103, 1269-1277.
2. Rock, E.P., *et al*, 1987: Comparative Analysis of the *Plasmodium falciparum* Histidine-Rich Proteins HRP-I, HRP-II, and HRP-III in Malaria Parasities of Diverse Origin. *Parasitol.*, 95, 209-227.
3. Parra, M.E., *et al*, 1991: Identification of *Plasmodium falciparum* Histidine-Rich Protein 2 in the Plasma of Humans with Malaria. *J. Clin. Microbiol.*, 29, 1629-1634.
4. Rodriguez-Del Valle, M., *et al*, 1991: Detection of Antigens and Antibodies in the Urine of Humans with *Plasmodium falciparum* Malaria. *J. Clin. Microbiol.*, 29, 1236-1242.

KEY TO SYMBOLS

Temperature limitation

Use by/Expiry date

IVD *In Vitro* Diagnostic

Harmful (Xn)