# SBio Malaria Pf Test

**Rapid test for *P. falciparum* malaria**

| | |
|---|---|
| REF | 90301025 |
| Σ | 25 T |

CE

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|---|---|---|---|---|
| Temperature Limitation | Manufacturer | PIPETTE — Disposable Plastic Sample Applicator | EC REP — Authorised Representative in the European Community | Xn<br>$NaN_3$ R22 S23-46-61<br>Harmful if swallowed.<br>Do not breathe vapour.<br>If swallowed, seek medical advice immediately and show this container or label.<br>Avoid release to the environment.<br>Refer to special instructions. |
| Use by (Last day of stated month) | Consult Instructions for use | DEVICE — Device | BUF — Assay Buffer | |
| Date of Manufacture | REF — Catalogue Number | Σ — Contains sufficient for <n> tests | Do not reuse | |
| LOT — Batch Number/ Lot Number | IVD — *In vitro* Diagnostic Medical Device | This side up | Malaria Pf — Rapid test for *P. falciparum* malaria | |

## INTENDED USE

SBio Malaria Pf Test is a rapid, qualitative, two site sandwich immunoassay for the determination 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 viz. *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 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. falciparum* species. SBio Malaria Pf Test detects the presence of Pf. HRP-2 in whole blood specimen and is a sensitive and specific test for the detection of *P. falciparum* malaria.

## PRINCIPLE

SBio Malaria Pf Test is a rapid test for the detection of *P. falciparum* malaria that utilizes the principle of immunochromatography. As the test sample flows through the membrane assembly of the device after addition of the clearing buffer, the colored monoclonal anti Pf. HRP-2 (IgG) colloidal gold conjugate 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 monoclonal anti Pf. HRP-2 (IgM) antisera coated on the membrane leading to formation of a pink-purple colored band which confirms a positive test result. Absence of this colored 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-purple band. The control band formation is based on the 'Rabbit / anti-Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance.

## REAGENTS AND MATERIALS SUPPLIED

SBio Malaria Pf Test kit contains :

A. Individual pouches, each containing :
   1. Device: Membrane assembly predispensed with anti Pf. HRP-2 (IgG) antisera-colloidal gold conjugate, rabbit IgG-colloidal gold conjugate and anti Pf. HRP-2 (IgM) antisera and anti rabbit antisera at the respective regions.
   2. Desiccant pouch.
   3. Pipette: Disposable 5µl sample applicator.

B. Buf : 0.1 M diSodium tetraborate, 1% Triton X-100, with 0.1% Sodium Azide.

C. Package insert.

## OPTIONAL MATERIAL REQUIRED

Calibrated micro pipette capable of delivering 5 µl sample accurately.

## STORAGE AND STABILITY

The test kit may be stored between 4-45ºC till the duration of the shelf life as indicated on the pouch / carton. DO NOT FREEZE.

## NOTES

1. Read the instructions carefully before performing the test.
2. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
3. Do not use beyond expiry date.
4. Do not reuse the test device.
5. Do not intermix the reagents from different lots.
6. Handle all specimens as potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
7. Clearing Buffer contains Sodium Azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.

## SPECIMEN COLLECTION AND PREPARATION

Fresh anti coagulated whole blood should be used as 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 specimen may be stored at 2 - 8ºC for upto 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.

## TEST PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the SBio Malaria Pf Test kit components to room temperature before testing.
2. In case the pouch has been stored at 2 -8 ºC allow atleast 30 minutes for the device to come to room temperature.
3. Open the pouch and retrieve 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. Label the test device with patient/specimen identity.
5. Tighten the vial cap of the clearing buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
6. Evenly mix the anti coagulated blood sample by gentle swirling. Dip the sample applicator into the sample. Ensuring that a loop full of blood is retrieved, blot the blood so collected in the sample port 'A' (This delivers approximately 5µl of the whole blood specimen).

**OR**

In case finger prick blood is being used, touch the sample applicator to the blood on the finger prick. Ensuring that a loop full of blood is retrieved, immediately blot the specimen in the sample port 'A' (Care should be taken that the blood sample has not clotted and the transfer to the sample port is immediate).

**OR**

Alternatively, 5 µl of the anti coagulated or the finger prick specimen may be delivered in the sample port 'A' using a micro pipette.

NOTE: Ensure that the blood from the sample applicator has been completely taken up by the sample port 'A'.

7. Immediately dispense **two drops** of the clearing buffer into buffer port 'B' by holding the plastic dropper bottle vertically.
8. At the end of 20 minutes, read the results as follows:


**NEGATIVE** for *P. falciparum* malaria : Only one pink-purple colored band appears in the control window 'C'.


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



**INVALID** : The test should be considered invalid if the control band 'C' does not appear. The test is also invalid if only the test band and no control band appears. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

## PERFORMANCE CHARACTERISTICS

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

| Sample | Total no. of samples tested | SBio Malaria Pf | | Sensitivity (%) | Specificity (%) |
|---|---|---|---|---|---|
| | | +ve | -ve | | |
| Pf +ve | 74 | 73 | 1 | 98.6 | - |
| Pv +ve | 8 | 0 | 8 | - | 100 |
| Malaria -ve | 85 | 1 | 84 | - | 98.8 |

2. In an another independent study, 125 patient samples from a *P. falciparum* endemic area were tested with SBio Malaria Pf Test and microscopy (thick and thin smear). SBio Malaria Pf Test was found to be 100% sensitive and 100% specific to *P. falciparum* against microscopy. All the 31 samples that tested positive for *P. falciparum* under microscopy showed positive results with SBio Malaria Pf Test. The four *P. vivax* positive samples and the 90 malaria negative samples tested negative with SBio Malaria Pf Test.
3. In a third independent study, 100 patient samples were tested with SBio Malaria Pf Test, with another immunochromatographic test for *P. falciparum* and with microscopy. SBio Malaria Pf Test 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, SBio Malaria Pf Test is a highly sensitive and specific test for the diagnosis of *falciparum* malaria.

## LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, the parasitological techniques of reference should be considered (microscopic examination of the thick smear and thin blood films).
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
4. Interference due to presence of heterophile antibodies in patient's sample can lead to erroneous analyte detection in immunoassay, has been reported in various studies. SBio Malaria Pf Test uses HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit majority of this interference.
5. In *P. falciparum* malaria infection, HRP-2 is not secreted in gametogony stage. Hence, in "Carriers", the HRP-2 band may be absent.
6. Since the Pf. HRP-2 persists for upto a fortnight even after successful therapy, a positive test result does not indicate a failed therapeutic response.
7. In case the test needs to be used to monitor success of therapy, testing is advised only from 15 days after the completion of therapy.
8. Do not interpret the test results beyond 30 minutes.

## BIBLIOGRAPHY


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