







BIBLIOGRAPHY

1. Beadle C et al (1994) Diagnosis of Malaria detection of Plasmodium falciparum HRP-2 antigen with rapid antigen capture assay. Lancet 343, 564-568.
2. Facer C A (1994) Rapid malaria diagnosis an update . In Rapid Methods and Automation in Microbiology and Immunology. Intercept Ltd. PO Box 716 Andover Hampshire pp 129-143
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.

SYMBOLES USED

| | |
|---|------------------------------------|
|  | Consult instructions for use |
|  | Storage temperature |
|  | Use by |
| LOT | Batch code |
| REF | Catalogue number |
| IVD | In vitro diagnostic medical device |
| CARD | Test Device |
| PIPETTE | Disposable Plastic Dropper |
| BUF | Sample running buffer |
|  | Manufactured By |
|  | Date of Manufacture |
|  | Contains sufficient <n> tests |



Aspect Court, 4 Temple Row
Birmingham B2 5HG
UNITED KINGDOM

Version EN1 - 01/2005.



Core™ Malaria Pf

Rapid assay for the detection of Malaria Plasmodium falciparum in whole blood.
CAT N°: MAL-190020

INTRODUCTION

Core Malaria Pf is a rapid self performing, qualitative, two site sandwich immunoassay for the determination of P. falciparum specific histidine rich protein –2 (Pf HRP-2) in whole blood samples.

SUMMARY

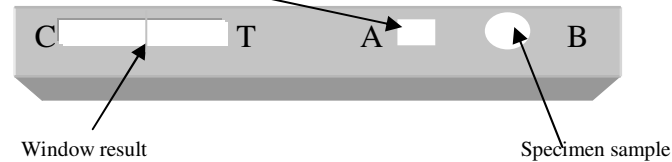
Core Malaria Pf is a rapid test based on the principle of Immunochromatography.

Four species of the Plasmodium parasites are responsible for malaria infections in human 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.

Core Malaria Pf 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

Sample running buffer



Core Malaria Pf 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 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 leading to formation of a pink 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 mouse antibodies coated on the membrane at the control region, forming a pink band. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

1 kit contain :

- 25 Individually pouched devices: Membrane assembly predispensed with anti Pf HRP-2 colloidal gold conjugated antisera, anti Pf. HRP-2 antisera and anti mouse antisera at the respective regions and sample applicator pipette.
- Clearing buffer in a dropper bottle.
- A capillary tube / applicator pipette
- Package Insert.

STORAGE AND STABILITY

The test kit may be stored between 4°C- 30°C till the duration of the shelf life as indicated on the kit and the pouch. DO NOT FREEZE.

NOTES

Read the instructions carefully before performing the test.

For in vitro diagnostic use only. NOT FOR MEDICINAL USE.

Do not use beyond expiry date.

Do not inter mix reagents from different lots.

Handle all specimens as potentially infectious.

Follow standard biosafety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND 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.

TEST PROCEDURE AND RESULTS INTERPRETATION

- Bring the Core Malaria Pf kit components to room temperature before testing.
- In case the pouch has been stored at 2– 8°C, allow at least 30 minutes for the device to come to room temperature. Check the colour of the desiccant. It should be blue. If it has turned colourless or faint blue, discard the device and use another device.
- Open the pouch and remove the device. Once opened, the device must be used immediately.
- Evenly mix the anti coagulated blood sample by gentle swirling. Touch the sample applicator pipette to the surface of the blood in the sample container. Blot the blood so collected on to the sample pad in the sample well 'A'. (This delivers approximately 5 µl of the whole blood specimen).

OR

In case finger prick blood is being used, touch the sample applicator pipette to the blood on the finger prick 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

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

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

- Dispense six drops (300 ul) of the clearing buffer into well 'B', by holding the plastic dropper bottle vertically.

6. At the end of 15 minutes, read the results as follows:

NEGATIVE:



POSITIVE:



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 appears also 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. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

TEST PERFORMANCES :

Detection Limit:

Based on the studies of Core Malaria Pf, the test detects presence of HRP-2, in the whole blood, qualitatively, at a threshold of 10 parasites per micro litre. No hook effect was observed up to 480000 parasites per micro litre.

❖ Sensitivity /Specificity

In a prospective study including 300 samples, Core Malaria Pf has given a sensitivity of 99% and a specificity of 96%.

❖ Interferences:

Negatives samples in Plasmodium falciparum and positive in Rhumatoid Factor (128 IU/ml, 192 IU/ml and 250 IU/ml) were tested and found negative. There were no interferences observed between RF and Plasmodium falciparum.

However the presence of RF could interfere and give false positive results.

❖ Cross Reactions

50 whole blood samples with the following pathologies: Leishmaniose viscérale, Trypanosomiase african, Toxoplasmose of primo-invasion, Plasmodium Ovale, Plasmodium malariae, Plasmodium vivax were tested. No cross reactions were observed.

❖ Reliability:

The result obtained with Core Malaria Pf by using known positives and negatives samples were fully correlated to results obtained on other commercially available reagents : (Kappa value > 0.92.)

❖ Precision inter and intra series :

20 negatives and positives samples were tested 10 times on 2 different lot. All positives samples were positives and all negatives samples were negatives.

Limitation of the Test:

- 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.
- 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.
- As with all diagnostic tests, the results must always be correlated with clinical findings.