Core Malaria Pv / Pf

Rapid Test for Malaria Pv/ Pf -(Device)

Ref: MAL-190022

INTRODUCTION

Core Malaria Pv/Pf is a self performing, qualitative, sandwich immunoassay for the detection and differentiation of vivax malaria and falciparum malaria in whole blood samples.

SUMMARY

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* and P. vivax are the most prevalent. Early detection and differentiation of malaria is of paramount importance due to incidence of cerebral malaria and drug resistance associated with falciparum malaria causing most of the morbidity and mortality world wide. ***Core Malaria Pv/Pf*** is based on the detection of an abundant intracellular metabolic enzyme produced by malarial parasites in the blood. The enzyme, Lactate DeHydrogenase (pLDH), is released from viable parasitized blood cells and is rapidly detected by a series of monoclonal antibodies. Differentiation between malarial species is based on antigenic differences between pLDH isoforms. Since the pLDH is the product of viable parasites the test may be used to monitor effective antimalarial therapy.

Core Malaria Pv/Pf detects the presence of vivax specific pLDH and falciparum specific pLDH in whole blood specimen and is a sensitive and specific test for the detection and differentiation of vivax malaria and falciparum malaria.

PRINCIPLE

Core Malaria Pv/Pf 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 pan specific pLDH colloidal gold conjugate (monoclonal) antisera complexes the pLDH in the lysed sample. This complex moves further on the membrane to the test region where it is immobilised by the anti vivax specific pLDH(monoclonal) antisera and/ or the anti falciparum specific pLDH coated on the membrane leading to formation of pink-purple colored band/s which confirms a positive test result. A band will appear under Pf at the test region in falciparum malaria positive samples, while a band will appear under Pv in vivax malaria positive samples. Appearance of band under Pf as well as Pv in the test region suggests a mixed infection..Absence of colored band/s 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. This control band serves to validate the test performance.

REAGENTS AND MATERIAL SUPPLIED

Core Malaria Pv/Pf kit contains:

A. Individually pouched devices:
   1. Membrane assembly predispensed with anti pan specific pLDH- colloidal gold conjugated antisera, rabbit antisera conjugated colloidal gold and anti vivax specific pLDH antisera, anti falciparum specific pLDH antisera , anti rabbit antisera at the respective regions.
   2. Desiccant pouch.
   3. 5 µl sample loop.

B. Clearing buffer in a dropper bottle.

C. Package insert

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 5µl sample accurately.

STORAGE AND STABILITY

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

NOTE

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 and kit materials.

SPECIMEN COLLECTION AND PREPARATION

Fresh blood from finger prick / puncture should be used as a test specimen. However, fresh anti coagulated whole blood may also 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 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.

PROCEDURE

1. Bring the kit components to room temperature before testing.
2. 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.
3. Open the pouch and remove the device. Once opened, the device must be used immediately.
4. Evenly mix the anti coagulated blood sample by gentle swirling. Dip the sample loop in to the sample .
   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 loop 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**

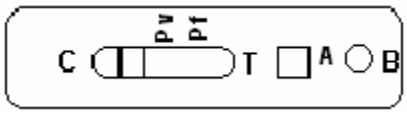
   Alternatively, 5µl of the anti coagulated or finger prick specimen may be delivered to the sample pad in the sample well 'A' using a micro pipette.

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

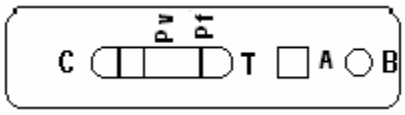
5. Dispense four drops of the clearing buffer into well 'B', by holding the plastic dropper bottle vertically.

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

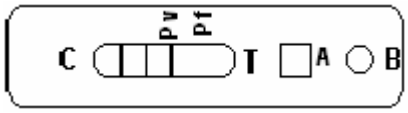
NEGATIVE for malaria :Only one colored band appears in the control window 'C'.



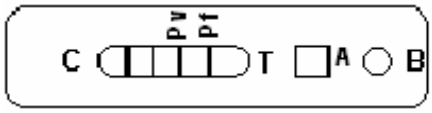
POSITIVE for *P.falciparum* malaria :In addition to the control band, a distinct colored band also appears under the region marked Pf in the Test window 'T'.



POSITIVE for *P.vivax* malaria :In addition to the control band, a distinct colored band also appears under the region marked Pv in the Test window 'T'.



POSITIVE for *P.falciparum* and *P.vivax* malaria :In addition to the control band, distinct colored bands appear under the region marked Pf and Pv in the Test window 'T'.



8. 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.

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, the results must always be correlated with clinical findings.
2. ***Core Malaria Pv/Pf*** is 100% sensitive to *P. falciparium* and *P. vivax* malaria.

PERFORMANCE CHRACTERISTICS

In an in house study a panel of 207 samples whose results were earlier confirmed with microscopy were tested with ***Core Malaria Pv/Pf*** **.** The results obtained are as follows:

Sample	Total No. of samples tested	***Core Malaria Pv/Pf***		Sensitivity	Specificity
		Positive	Negative		
P. Falciparum +Ve	22	22	0	100%	-
P. Vivax +Ve	17	17	0	100%	-
Malaria -Ve	168	0	168	-	100%

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