VISITECT® MALARIA Pf Ref OD026/ OD156

Rapid test for the determination of P. falciparum specific Histidine rich protein in Whole Blood.

Store at 4°C to 40°C. DO NOT FREEZE.

For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

Four species of the Plasmodium parasites are responsible for malaria infections in human: 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. The period of incubation, symptoms and duration of attack vary with the species and the individual's level of acquired immunity. Early detection of P.falciparum malaria is therefore of paramount importance due to the 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.

VISITECT MALARIA Pf. is a rapid, Point-of-Care, qualitative, two-site sandwich immunoassay for the determination of P.falciparum specific histidine rich protein – 2 (Pf HRP-2) in whole blood.
For professional use only.

PRINCIPLE OF THE TEST

VISITECT MALARIA Pf. is a rapid test for the detection of P.falciparum malaria that utilises the principle of Immunochromatography. As the test sample flows through the membrane assembly of the device, after addition of the diluent buffer, the coloured anti-Pf HRP-2 colloidal gold monoclonal antibody conjugate complexes with the Pf HRP-2 in the lysed sample. This complex moves further along the membrane to the test region where it is immobilised by the anti-Pf HRP-2 monoclonal antibody coated on the membrane, leading to formation of a pink coloured line which confirms a positive test result. Absence of this coloured line in the test region indicates a negative test result.
The unreacted conjugate, unbound complex, if any, and the colloidal gold conjugated rabbit IgG moves further along the membrane and is subsequently immobilised by the goat anti-rabbit IgG coated on the membrane at the control region, forming a pink line. This control line serves to validate the test performance.

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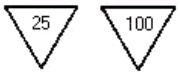
		
	25	100
Test Device		

Comprising of membrane assembly predispensed with anti-Pf HRP-2 colloidal gold conjugated monoclonal antibodies and colloidal gold conjugated rabbit IgG. Anti-Pf HRP-2 monoclonal antibodies on the test line and goat anti-rabbit IgG on the Control line. Disposable plastic dropper (5µl drop size). Desiccant bag.

Buf	**8.5 ml**	**4 X 8.5 ml**

Diluent Buffer. Solution of Trizma-Base and Triton X-100

INSTRUCTION LEAFLET	1	1

PRECAUTIONS

VISITECT reagents do not contain dangerous substances as defined by current UK Chemicals (Hazardous Information and Packaging for Supply) regulations. All reagents should, however, be treated as potential biohazards in use and disposal. Final disposal must be in accordance with local legislation. Do not ingest.

VISITECT MALARIA Pf. Diluent buffer contain 0.095% sodium azide as a preservative which may be toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.

STORAGE

Reagents must be stored at temperatures between 4°C to 40°C.

The kit will perform within specification until the stated expiry date as determined from date of product manufacture and stated on kit and components. Expiry date is the last day of the month on the pouch and the kit label. Do not use reagents after the expiry date.

Exposure of reagents to excessive temperatures should be avoided. Do not expose to direct sunlight.

DO NOT FREEZE DEVICE as this will cause irreversible damage.

SPECIMEN COLLECTION AND PREPARATION

Obtain a sample of venous blood from the patient and add to plasma collection vial.

Do not use contaminated or lipaemic samples for testing as this will adversly affect the results.

Samples may be stored at 2°C to 8°C for up to 72 hours prior to testing.

Fresh whole blood samples may also be used with this kit. See Assay procedure for methodology.

REAGENT PREPARATION

Devices and samples should be brought to room temperature (20°C to 25°C) and mixed gently prior to use.

In case the pouch has been stored at 4°C to 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.

LIMITATIONS OF USE

The use of samples other than whole blood or EDTA, Heparin or Citrate samples have not been validated in this test.

There is no reuse protocol for this product.

A low or suspected positive result should be re-assessed. Diagnosis should not be made solely on the findings of one clinical assay. When making an interpretation of the test it is strongly advised to take all clinical data into consideration.

Since the Pf HRP-2 persists for up to a two weeks (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.

ASSAY PROCEDURE

1. Open the pouch and remove the device. Once opened, the device must be used immediately.
2. 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 5µl 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

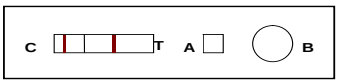
   Alternatively, 5µl of the anti-coagulated or finger prick specimen may be delivered to the sample pad in the sample well 'A' using a micropipette.

   NOTE: Ensure the blood from the sample applicator pipette has been completely taken up by the sample pad.
3. Dispense six drops of the diluent buffer into well 'B', by holding the plastic dropper bottle vertically.
4. At the end of 15 minutes, read the results

RESULTS AND INTERPRETATION

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

Positive: for P.falciparum malaria: In addition to the control line, a distinct pink coloured line also appears in the test window "T".



The test should be considered invalid if no line appears. Repeat the test with a new device.

The test should not be interpreted after 15 minutes.

TROUBLESHOOTING

Use a separate disposable sample applicator pipette for each sample to prevent cross contamination.

Prior to the start of the assay bring all reagents to room temperature (20°C to 25°C).

For use by operatives with at least a minimum of basic laboratory training.

Do not use damaged or contaminated kit components.

EVALUATION DATA

Reproducability of **VISITECT MALARIA Pf** is 100% (+/- one double dilution).

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

Sample Type	Total No. of Samples Tested	**VISITECT Malaria Pf**		Sensitivity %	Specificity %
		+	-		
P.falciparum	74	73	1	98.6	-
P.vivax Positive	8	0	8	-	100
Malaria Negative	85	1	84	-	98.8

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

REFERENCES

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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 Parasites 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.
5. Data on file, Omega Diagnostics Ltd.

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