

Size : 137 x 218 mm



RAPID TEST FOR MALARIA

Pan / Pf

DEVICE

INTENDED USE

malascan[®] PLUS is a rapid, self performing, qualitative, two site sandwich immunoassay utilizing whole blood for the detection of *P.falciparum* specific histidine rich protein-2 (Pf. HRP-2) and Pan malaria specific pLDH. The test may also be used for the differentiation of *P. falciparum* and other malarial species and for the follow up of antimalarial therapy 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 utmost importance due to incidence of cerebral malaria and drug resistance associated with falciparum malaria and due to the morbidity associated with the other malarial forms.

malascan[®] PLUS detects the presence of Pan malaria specific pLDH released from parasitised blood cells, for the detection of all malarial parasites. Whereas, for the detection of *P. falciparum* malaria, **malascan**[®] PLUS utilises the detection of *P. falciparum* specific histidine rich protein-2 (Pf. HRP-2) which is a water soluble protein that is released from parasitised erythrocytes of infected individuals.

In the absence of *P.falciparum* specific Pf. HRP-2, the presence of Pan malaria specific band points to the presence of other malarial species such as *P.vivax*, *P.ovale* or *P.malariae*. Speciation is done and results inferred in the context of prevalence rates of the malarial species prevalent in the particular region.

Since pLDH is a product of viable parasites, the Pan band may also be used to monitor success of antimalarial therapy.

PRINCIPLE

malascan[®] PLUS Antigen utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immunochromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly of the device after addition of the clearing buffer, the colored colloidal gold conjugates of the Agglutinating Sera for HRP-2 and the Agglutinating Sera for Pan malaria specific pLDH complexes the HRP-2/ pLDH in the lysed sample. This complex moves further on the membrane to the test region where it is immobilized by the Agglutinating Sera for HRP-2 and / or Agglutinating Sera for Pan malaria specific pLDH coated on the membrane leading to formation of pink-purple colored band/s which confirms a positive test result. While both the bands will appear at the test region in falciparum positive samples, only one band will appear in non- falciparum malaria positive samples. Absence of this 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 immobilized by Agglutinating Sera for Rabbit globulin coated on the membrane at the control region, forming a pink-purple band. The control band formation is based on the 'Rabbit globulin / Agglutinating Sera for 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

malascan[®] PLUS kit contains:

A. Individual pouches, each containing:

1. **DEVICE** Membrane assembly pre-dispensed with Agglutinating Sera for HRP-2 - colloidal gold conjugate, Agglutinating Sera for Pan malaria specific pLDH - colloidal gold conjugate, Rabbit globulin colloidal gold conjugate, Agglutinating Sera for HRP-2, Agglutinating Sera for Pan malaria specific pLDH and Agglutinating Sera for Rabbit globulin at the respective regions.
2. Desiccant pouch.
3. **PIPETTE** Disposable Plastic Sample Applicator.

B. **BUF** Clearing Buffer in a dropper bottle.

C. Package Insert.

REF	503140010	503140025	503140050
	10	25	50

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 5µl sample accurately.

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit components may be stored between 1°C to 40°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE. After first opening of the clearing buffer bottle, it can be stored between 1°C to 40°C for the remaining duration of its shelf life.

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 intermix the reagents from different lots. Handle all specimens as potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infective material. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

Fresh anti coagulated whole blood should be used as a test sample. EDTA or CPDA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants. 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°C to 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.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the **malascan[®] PLUS** kit components to room temperature before testing.
2. Open the pouch and retrieve the device, sample applicator and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the device and use another device. **Once opened, the device must be used immediately.**
3. Label the test device with patient's identity.
4. Tighten the cap of the clearing buffer bottle provided with the kit in the clockwise direction to pierce the buffer bottle nozzle.
5. Evenly mix the anti coagulated blood sample by gentle swirling. Dip the sample applicator into the sample. Ensuring that an applicator 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

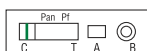
In case finger prick blood is being used, touch the sample applicator to the blood on the finger prick. Ensuring that an applicator full of blood is retrieved, immediately blot the specimen in the sample port 'A'. (Care should be taken that the blood sample has not clotted and the transfer to the sample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

OR

Alternatively, 5µl of the anti coagulated or 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 at the sample port 'A'.

6. Immediately dispense **two drops** of clearing buffer into buffer port 'B', by holding the buffer bottle vertically .
7. Read the results at the end of **20 minutes** as follows :



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



POSITIVE for *P. falciparum* or mixed infection: In addition to the control band, two pink-purple bands appear at regions 'Pf' and 'Pan' in the test window 'T'.



POSITIVE for Other species (non falciparum): In addition to the control band, one pink-purple band appears only at region 'Pan' in the test window 'T'.



INVALID RESULT: The test should be considered invalid if no bands appear on the device. The test should also be considered invalid if only test bands (Pan and/or Pf) appear and no control band appears. Repeat the test with a new device ensuring that the test procedure has been followed accurately.

PERFORMANCE CHARACTERISTICS

In an in-house study, a panel of 251 samples whose results were earlier confirmed with microscopy were tested with

malascan® PLUS. The results obtained are as follows:

Sample	Total No. of samples tested	malascan® PLUS		Sensitivity (%)	Specificity (%)
		Positive	Negative		
<i>P. falciparum</i> positive	16	16	0	100	-
<i>P. vivax</i> positive	25	25	0	100	-
Malaria negative	210	0	210	-	100

LIMITATIONS OF THE TEST

- As with all diagnostic tests, the test result must always be correlated with clinical findings.
- 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).
- Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
- 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. **malascan® PLUS** uses HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit majority of these interferences.
- In case of mixed infection (*P.falciparum*, with other malarial species), both, 'Pf' and 'Pan' malaria bands will be positive. Hence, differentiation of infection due to *P.vivax*, *P.ovale* or *P.malariae* cannot be done.
- While monitoring therapy, using the 'Pan' band, if the reaction of the test remains positive with the same intensity after 5-10 days, post treatment, the possibility of a resistant strain of malaria has to be considered.
- Usually, the 'Pan' band turns negative after successful anti malarial therapy. However, since treatment duration and medication used affect the clearance of parasites, the test should be repeated after 5-10 days of start of treatment.
- In *P.falciparum* malaria infection, HRP-2 is not secreted in gametogony stage. Hence, in "Carriers", the HRP-2 band may be absent.
- HRP-2 levels, post treatment persists upto 15 days, the 'Pan' band can be used to monitor success of therapy in *P.falciparum* malaria cases.
- In a few cases, where the HRP-2 band is positive and the 'Pan' malaria band is negative, it may indicate a case of post treatment malaria. However, such a reaction pattern may also be obtained in a few cases of untreated malaria. Retesting after 2 days is advised, in such cases.
- Do not interpret the test results beyond 30 minutes.

WARRANTY









This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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13. Data on file: Viola Diagnostic Systems.

SYMBOL KEYS

	Temperature Limitation		Consult Instructions for use		Date of Manufacture
	Manufacturer	IVD	In vitro Diagnostic Medical Device		This side up
	Use by	REF	Catalogue Number	DEVICE	Device
	Contains sufficient for <n> tests	LOT	Batch Number / Lot Number	PIPETTE	Disposable Plastic Sample Applicator
	Do not reuse	BUF	Clearing Buffer		



Manufactured by:

Viola Diagnostic Systems

A Division of Tulip Diagnostics (P) Ltd.

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