

MALERISCAN[®]

MALARIA

P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test

For Professional Use

A Rapid test for the qualitative detection of Pf HRP-II, Pf pLDH and PAN LDH of Malaria parasite in human whole blood



Read pack Insert before use provided along with the kit



REF MAT- PF/PAN - 50

Intended Use : MALERISCAN[®] MALARIA P.f/PAN (Pv,Pm, Po) 3 Line Antigen Test is an immunochromatographic based assay for the qualitative detection of Plasmodium lactate dehydrogenase (PAN LDH) specific to Malaria Pv, Pm, Po and HRP II, pLDH antigens specific to Pf in human whole blood.

Introduction :

Malaria is a serious, sometimes fatal, parasitic disease characterized by fever, chills, and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds of malaria parasites that can infect humans: Plasmodium falciparum, P.vivax, P.ovale, and P. malariae. In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites. The Maleriscan Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen test is an immunochromatographic (rapid) Test for the qualitative detection of antigens specific to Plasmodium falciparum and Plasmodium vivax in human whole blood.

Test Principle :

The MALERISCAN MALARIA P.f/PAN (Pv, Pm, Po) 3 Line Antigen test contains a membrane strip which is precoated with monoclonal antibody specific to Histidine Rich Protein II (HRP II) and Plasmodium Lactate dehydrogenase (pLDH) of the plasmodium falciparum Species on test band 1(P.f) and another type monoclonal antibody specific to PAN LDH of the Plasmodium Sp. Vivax, Malariae and Ovale on test band 2 (PAN). The Malaria antibody colloidal gold conjugate and sample moves along the membrane chromatographically to the test region (P.f & PAN) and forms a visible line as the antibody antigen Malaria antibody gold particle complex forms with high degree of sensitivity and specificity. This test device has a letter of Pf, PAN and C as "Test Line" and "Control Line" on the surface of the case. Both the Test Line (Pf) & Test line (PAN) and Control Line (C) in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the reagents are working.

Storage And Stability :

Kit should be stored between 2°C-30°C in the sealed pouch. The kit is stable until the expiry date mentioned on the pouch when stored under the above conditions.

The diluent bottle once opened is stable for 2 years.

Pack Size : Available in Packs of 50 Tests

Contents Of The Kit :

PACK SIZE	50 Tests
Test Device	50 Nos.
Diluent	6.5 ml x 2
5µl Dropper	50 Nos.
Silicagel	50 Nos.

Material required but not provided :

- Sterilized vial
- Disposable gloves
- Precision pipette
- Sodium hypochlorite solution (free available chlorine 50-500mg/L)
- Autoclaved Tips

Warnings & Precautions :

In order to obtain reproducible results, the following rules must be observed:

- Read this Pack Insert carefully.
- DO NOT FREEZE THE KITS. If refrigerated the kits should be brought to room temperature before testing. Assay should be conducted between 15-30° C.
- Do not use umbilical cord blood because it prevents colloidal gold from migrating & can interfere with results.
- Do not use the kits beyond their expiry date.
- Use only whole blood.
- Carefully observe the prescribed number of drops to be added, 5µl of whole blood and 4 drops of diluent only.
- Use the test device soon after it is removed from the pouch.
- Do not use the test device, if the pouch seal is broken.
- Avoid any contamination among samples; for this purpose, disposable tips and sterilized vial should be used for each sample and reagent.
- Read the result in 20 minutes. DO NOT INTERPRET THE RESULT AFTER 20 MINUTES.
- Do not smoke, eat drink or apply cosmetics during the assay.
- For In vitro Diagnostic Use only.
- For single use only.
- Do not use the whole blood sample, which is stored for more than 3 days - Because it may give false positive result.

- All human serum and plasma samples should be considered potentially infectious. It is recommended that all specimens of human origin should be handled as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control / National Institute of Health manual "Biosafety in Microbiological and Biomedical Laboratories", 1984.
- Never pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled. Afterwards wash hands carefully.
- Avoid splashing or forming aerosols.
- Discard all materials and specimens as if capable of transmitting infection.
- The preferred method of disposal is autoclaving for a minimum of one hour at 121°C. Liquid waste not containing acid may be mixed with sodium hypochlorite in volumes such that the final mixture contains 50-500 mg/l available chlorine. Allow 30 minutes for decontamination.

Note : Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite.

- Spills should be wiped up thoroughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to biohazardous waste matter for proper disposal.
- Reagents are stored between 2-30°C. Avoid unnecessary exposure to light. Do not use reagents after expiration date.
- Do not mix or interchange reagents from different kits or kit batches. Cross contamination of reagents or samples can cause erroneous results.
- Use a new pipette tip for each sample.
- Optimal results are obtained by strictly adhering to the test protocol. Accurate and precise pipetting, as well as following the exact time and temperature requirements, is essential. Once the assay has been started, all steps should be performed without interruption.

Specimen : Fresh whole blood

Specimen collection & Preparations (Collection by Veni Puncture) :

- Collect whole blood into a sterilized vial (Containing EDTA, Citrate or Heparin) by veni puncture.
- If specimens are not immediately tested, they should be refrigerated at 2-8°C.
- When stored at 2-8°C the whole blood sample should be used within 3 days.

Collection using a lancet :

- Clean the area to be lanced with an alcohol swab.
- Squeeze the end of the finger and pierce with a sterile lancet.
- Wipe away the first drop of blood with sterile gauze or cotton.
- Using the dropper provided, while gently squeezing the thumb immerse the open end in the blood drop and then gently release the pressure to draw blood into the dropper.

Assay Procedure :

- Bring the kit and samples to Room Temperature.
- Remove the device from the pouch just prior to testing.
- Place the device on a flat surface.
- Add 5µl of whole blood (Fill the sample up to the mark in the dropper provided) into the sample window (S).
- Add 4 drops of diluent provided in the dropper bottle into the diluent window (D).
- Read the results in 20 minutes.
DO NOT READ ANY RESULT BEYOND TWENTY MINUTES.
- Any line appearing after 20 minutes would be of no diagnostic value.



Note :

If the background is not clear, then add 1 additional drops of diluent into the diluent window.

Interpretation of Test Results :

1. **Negative:** If only one red line (Control Line) appears in the result area, interpret the result as negative. This shows that the specimen does not contain antigens to Malaria. (Fig. A).



2. **Positive :**

a) If two red lines (Control & P.f.) appear in the result area, the specimen is reactive for antigens to P.f. (Fig. B).



b) If three red lines (Control, PAN and Pf) appear in the results area, then the specimen is reactive for antigens to P.f., P.v., P.m. or P.o. (Fig. C).



c) If two red lines (Control & PAN) appear in result area, the specimen is reactive for antigens to P.v, P.m., or P.o., (Fig. D).



3. **Invalid :** If no line appears or only test line appears after the test is complete, interpret the result as invalid. This shows that the test has been performed incorrectly or there was some procedural error. Please check the procedure and retest using a new device. (Fig. E)



Important : Test line either dark or light in colour (Red) should be considered reactive for antigens to malaria.

Sensitivity :

The MALARISCAN[®] MALARIA P.f/PAN (Pv,Pm, Po) 3 Line Antigen test device kit is able to detect parasitemia levels of 100-200 Parasites per µl of blood.

Specificity :

The test card can detect the presence of pLDH, an enzyme produced both in the sexual and asexual forms of the parasite. The presence of pLDH is tested using monoclonal antibodies directed against isoforms of the enzyme. Monoclonal antibody to LDH of plasmodium vivax has no cross reactivity with the human LDH, because Monoclonal antibody to LDH of plasmodium vivax was absorbed to LDH of human.

The test card can detect the presence of Histidine Rich Protein II (HRP II) of Plasmodium falciparum Species.

Performance Characteristics :

The MALARISCAN[®] MALARIA P.f/PAN (Pv,Pm, Po) 3 Line antigen test has been tested with positive and negative clinical samples tested by microscopic examination of whole blood.

A.Malaria Pf Sensitivity and Specificity

No. of positive Samples tested	No. of positive by MALARISCAN [®] MALARIA P.f/PAN (Pv,Pm, Po) 3 line Antigen Test	Sensitivity	No. of negative Samples tested	No. of positive by MALARISCAN [®] MALARIA P.f/PAN (Pv,Pm, Po) 3 line Antigen Test	Specificity
100	98	98%	200	199	99.5%

B.Malaria PAN Sensitivity and Specificity

No. of positive Samples tested	No. of positive by MALARISCAN [®] MALARIA P.f/PAN (Pv,Pm, Po) 3 line Antigen Test	Sensitivity	No. of negative Samples tested	No. of positive by MALARISCAN [®] MALARIA P.f/PAN (Pv,Pm, Po) 3 line Antigen Test	Specificity
100	98	98%	200	199	99.5%

Limitation of the test :

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. Anti-coagulants such as heparin, EDTA and citrate do not affect the test result.

REFERENCES :

1. Leonard K. Basco, Frederique Marquet, Michael M. Makler, and Jacques Le Bras: Plasmodium falciparum and Plasmodium vivax: Lactate Dehydrogenase Activity and its application for in vitro Drug susceptibility assay. Experimental parasitology 80, 260-271 (1995).
2. Robert Piper, Jacques Le Bras, Laura Wentworth, Angela Hunt-cooke, Sandra Houze, Peter Chiodini, and Michael Makler: Immunocapture Diagnostic Assays for Malaria using Plasmodium Lactate Dehydrogenase (pLDH). Am. J. Trop. Med. Hyg 60 (1), 1999, pp 109-118.
3. David R. and et. al. A Longitudinal Study of Type-Specific Antibody Responses to Plasmodium falciparum Merozoite Surface Protein-1 in an Area of Unstable Malaria in Sudan. Journal of Immunology, 161:347-359

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL

	Temperature Limitation		Date of Manufacture
	In vitro Diagnostic Device		Batch Code
	Company name & address		Refer Operating Instructions
	Use by		Company name
	Authorized Representative in European Community		Do Not Reuse
	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE
	NEGATIVE CONTROL		POSITIVE CONTROL