Malarigen (*P.f/P.v* Antigen) *Rapid Card Test*

INTENDED USE

Malarigen is a rapid card test for qualitative detection of malaria parasite antigens of *Plasmodium falciparum (P.f) & Plasmodium Vivax malaria* in human whole blood. The test is very sensitive & specific.

INTRODUCTION

Malaria is a parasitic disease caused by plasmodium transmitted from one human to another by bites of infected Anopheles mosquitos.

Malaria antigens currently targeted by rapid diagnostic test are Lactate dehydrogenase (pLDH) , Histidine rich protein (HRP-2) and Aldolase.

PRINCIPLE OF THE TEST

Four species of the Plasmodium parasites are responsible for malaria infection in human: P.falciparum(P.f), P.vivax (P.v), P.ovale(P.o) and P.malariae(P.m). The Malaria P.f/Pv kit is a rapid test for the detection of P.f malaria, and P.v malaria infections that utilizes the principle of Immunochromatography. This kit is intended for the detection of malaria infection in human blood sample, indicating differential diagnosis between HRP II (Histidine rich protein II) specific to P.f and pLDH (plasmodium Lactate Dehydrogenase) P.v specific to Plasmodium species. As the test sample flows through the membrane of the test device, after addition of the buffer, the anti-pLDH and the anti-P.f HRP-II coloured colloidal gold monoclonal antibody conjugates complex with the pLDH and P.f HRP-II, if present in the lysed sample. This complex moves further along the membrane to the test region where it is immobilized by the anti-pLDH and anti-P.f HRP-II monoclonal antibodies coated on the membrane, leading to formation of pink coloured lines, which confirms a positive test result.

MATERIAL PROVIDED

1. Test Devices
2. Buffer Vial
3. Sample Droppers/Loops
4. Pack Insert

KIT PRESENTATION

10/30/50 Tests

STORAGE AND STABILITY

The Malarigen P.f/P.v Rapid Test kit should be stored between 2-40°C. The Malarigen P.f/P.v Rapid Test will remain stable until the expiration date printed on the kit.

PRECAUTIONS

1. For *In vitro* diagnostic use only.
2. Do not use the kit after the expiry date.
3. Opened device must be used immediately.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. After use, dispose off all the samples and kit component as per rules of Bio medical waste handling and management.

SPECIMEN COLLECTION AND STORAGE

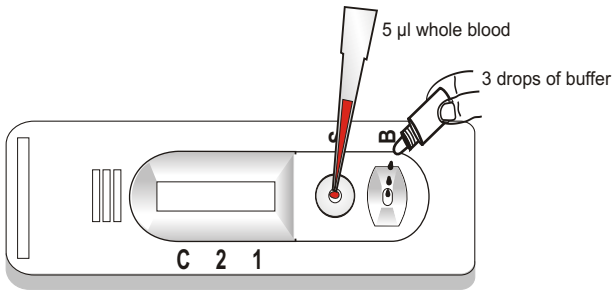
1. The test should be performed with **venous blood** collected in the sample tube containing anticoagulant or **Freshly collected blood from the finger tip** can be used as a sample.
2. Store the specimen at **2–8°C.** For the longer storage, please keep the sample below **-20°C**.

TEST PROCEDURE

Note: Bring the test device, buffer vial and sample to the room temperature if stored at 2–8°C.

Take out the test device from the pouch and place on a clean & flat surface.

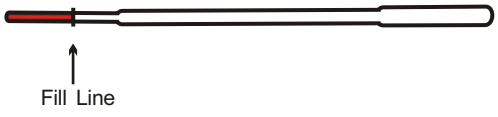
1. Add 5 µl of **whole blood** using **pipette** into **sample well** of test device. Followed by **3 drops** (90 -100µl) of **buffer** into **buffer well**.



Note: At 5 minutes, If background very dark then add **one more drop of buffer** in buffer well & read the results on clearance of background.

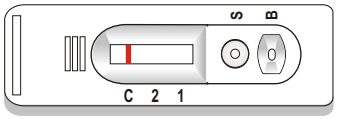
Read result at 20 minutes. (Do not interpret results after 30 minutes).

[If **Pipette** not available , **only then**, use the dropper provided. When using a sample dropper (**5µl**) take sample upto the fill line as Indicated in the diagram below]

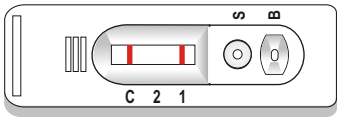


INTERPRETATION OF RESULTS

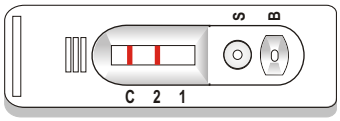
NEGATIVE: Only one pink/purple line at **C**



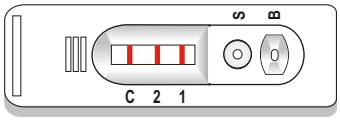
POSITIVE: Pink / Purple lines at **C & 1 : P. Falciparum Positive**



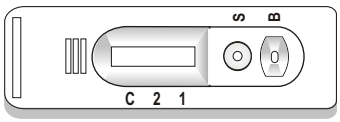
: Pink/Purple lines at **C & 2 : P. vivax Positive**



: Pink / Purple lines at **C, 1 & 2 : P. falciparum or P. falciparum & P. Vivax: Positive**



INVALID: If control line does not appear, the test is invalid. In this case, please repeat the test using another device following the test procedure correctly.



PERFORMANCE CHARACTERISTICS

The Malarigen (P.f/P.v Antigen) Rapid Test has been evaluated with positive and negative clinical samples tested by microscopic-examin ation (Giemsa Staining) and PCR.

Sample	Total no. of samples tested	Malarigen P.f/P.v Rapid Device test		sensitivity (%)	Specificity (%)
		Positive	Negative		
Malaria Negative	200	1	199	-	99.5
P. falciparum Positive	20	20	0	100	-
P. vivax Positive	25	25	0	100	-

LIMITATIONS OF THE TEST

1. The Malarigen P.f /P.v is designed for primary screening test.
2. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.
3. If the concentration of pLDH in the sample is very high, only test line may be observed. This is due to hook's effect. Such samples should be diluted 1:10 or more with negative blood (Human) & again re-run the test, Diluted sample should show both control & test line. In case, if control line does not appear or is faint dilute the sample further.
4. In most of the cases, after successful anti-malarial therapy the Pan band will turn negative. However, depending on the medication used, the clearance of parasite may take longer and the reaction of the test may remain positive. In such cases the test should be repeated after 5-10 days of start of treatment.
5. The possibility of resistant strain of malaria should always be considered if the reaction of the test remains positive with the same intensity after 5-10 days post treatment.

REFERENCES

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   Chai, I. H., et al. 1994. Occurrence of tertian malaria in a male
2. patient who has nerver been abroad. Korean J. Parasitol. 32: 195-200
3. Perlmann, P. and Troye-Blomberg, M. 2002. Malaria parasites and disease. Malaria Immunology. Chapter 1:1-4
4. Warhurst, D.C., and J. E. Williams. 1996. Laboratory diagnosis of malaria. J. Clin. Pathol. 49: 533-538
5. Kawamoto, F. 1991. Rapid diagnosis of malaria by fluorescence microscopy with light microscope and interference filters. Lancet. 337: 200-202.
6. Snounou, G., et al. 1993. Identification of the four human malaria parasite species in field samples by the polymerase chain reaction and detection of a high prevalence of mixed infections. Molecular and Biochemical Parasitology. 58: 283-292.

DISCLAIMER

While every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and / or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

WARNING

The Manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, cost or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.