



# Malarigen (P.f/Pan Antigen) Rapid Card Test

Malarigen

## INTENDED USE

Malarigen is a rapid card test for qualitative detection of malaria parasite antigens of *Plasmodium falciparum* (P.f) & *Pan malaria* (P.Vivax / P. malariae / P.ovale) 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/Pan kit is a rapid test for the detection of P.f malaria, and Pan malaria (P.Vivax / P. malariae / P.ovale) 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) pan 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 Loops / droppers
4. Pack Insert

## KIT PRESENTATION

30/50 Tests

## STORAGE AND STABILITY

The Malarigen P.f/Pan Rapid Test kit should be stored between 2-30°C. The Malarigen P.f/Pan 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

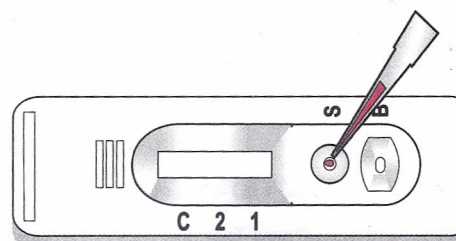
1. The test should be performed with **venous blood** collected in the sample tube containing anticoagulant or **Freshly collected blood from the finger tip** can be used as a sample.
2. Store the specimen at 2-8°C. For the longer storage, please keep the sample below -20°C.

## TEST PROCEDURE

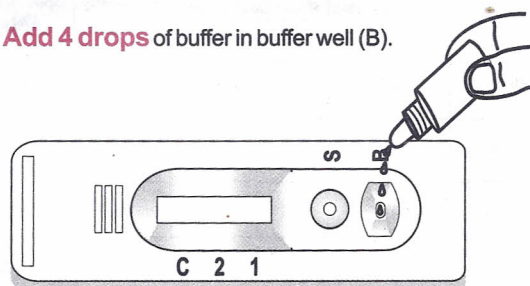
**Note:** Bring the test device, buffer vial and sample to the room temperature if stored at 2-8°C.

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

1. Add 5 µl of whole blood into sample well (S)



2. Add 4 drops of buffer in buffer well (B).



Read result at **15 minutes**. (Do not interpret after 30 minutes).