RAPINDO™
Malaria Pan/Pf

Device

INTENDED USE
RAPINDO™ Malaria Pan/Pf is a rapid, 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.
The test is intended for professional use at clinical and point of care sites in suspected cases of malaria infection.

SUMMARY
Five species of the Plasmodium parasites are responsible for malaria infections in human viz. *P. falciparum, P.vivax, P. ovale, P. malariae* and *P. knowlesi*. 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.
RAPINDO™ Malaria Pan/Pf 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, RAPINDO™ Malaria Pan/Pf 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*, *P. malariae or P. knowlesi.* 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
RAPINDO™ Malaria Pan/Pf utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography 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 / Agglutinating sera for Pan malaria specific pLDH - colloidal gold conjugate complexes the proteins in the lysed sample. This complex moves further on the membrane to the test region where it is immobilised by the Agglutinating sera for HRP-2 / 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 uncreated conjugate along with the rabbit globulin-colloidal gold 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 / 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
RAPINDO™ Malaria Pan/Pf kit contains:

A. Individual pouches, each containing:
   1. DEVICE Test 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. PIPETTE Disposable Plastic Sample Applicator.
   3. Desiccant pouch.

B. BUF Clearing Buffer in a dropper bottle.

C. Package Insert.

OPTIONAL MATERIAL REQUIRED
Calibrated micropipette capable of delivering 5μl sample accurately.

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STORAGE AND STABILITY

RAPINDO™ Malaria Pan/Pf products contains kits packed in individually sealed pouches that should storage at temperatures between 1°C and 40°C. Once the pouch is opened, the test kits inside must be used immediately. The shelf life of the test kits under sealed conditions is 24 months. Clearing buffer should be stored at a temperature between 1°C and 40°C. The shelf life of the reagents is 24 months from the first opened. DO NOT FREEZE THIS PRODUCT.

NOTES

1. Read the instructions carefully before performing the test.
2. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use.
3. The test is not intended for use in screening of asymptomatic population.
4. Do not use beyond expiry date.
5. Do not intermix components of different lots.
6. The device & sample applicator are for single use only.
7. 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.
8. Handle all specimens as potentially infectious.
9. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
10. Clearing buffer contains Sodium Azide(0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

SPECIMEN COLLECTION AND PREPARATION

Fresh blood from finger prick / puncture may be used as a test specimen. However, 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 upto 72 hours before testing. Clotted or contaminated blood samples should not be used for performing the test.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the **RAPINDO™ Malaria Pan/Pf** kit components to room temperature before testing.
2. Open the pouch and retrieve the device 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. Place the testing device on a flat horizontal surface.
5. Tighten the vial cap of the clearing buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
6. Evenly mix the anti coagulated blood sample by gentle swirling. Dip the sample applicator provided in the kit, into the sample. Ensuring that a 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).

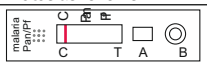
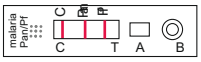
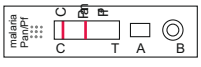
   OR

   In case finger prick blood is being used, touch the sample applicator to the blood on the finger prick. Ensuring that a 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'.
7. Immediately dispense two drops of clearing buffer into buffer port 'B', by holding the plastic dropper bottle vertically .
8. Read the results at the end of 20 minutes as follows :

		**NEGATIVE for malaria:** Only one pink-purple band appears in the control region 'C'.
		**POSITIVE for *P. falciparum* or mixed infection:** In addition to the control band, two pink-purple bands appear at regions 'Pf' and 'Pan' or only one pink-purple band appears at region 'Pf' .
		**POSITIVE for Other species (non falciparum):** In addition to the control band, one pink-purple band appears only at region 'Pan'.