LordsMed Malaria Pf/PAN Antigen Rapid test

Catalog No.	Pack Size	Specimen Type
MPNLMR01	25 Test Device	WholeBlood
MPNLMR02	50 Test Device	WholeBlood

INTENDED USE

LordsMed Malaria Pf/PAN Ag Rapid test is in vitro, qualitative lateral flow immunoassay for the detection of *P.falciparum* specific histidine rich protein-2 *(Pf. HRP-2*) and PAN malaria specific *p*LDH from human whole blood samples. The test may also be used for the differentiation of *P. falciparum* and other malarial species and for the follow up of anti-malarial therapy in whole blood samples. This is a rapid, in vitro, qualitative lateral flow immunoassay for the detection of P. falciparum specific histidine rich protein-2 (Pf. HRP-2) and PAN malaria specific PLDH from human wholeblood samples. The test may also be used for the differentiation of P. falciparum and other malaria species and for the follow up of anti- malaria therapy in whole blood samples. It is intended for professional use only.

PRINCIPLE

LordsMed Malaria Pf (HRP2)/PAN (*p*LDH) Ag Rapid Test contains a membrane strip, which is pre-coated with two test lines and one control line. One monoclonal antibody (Pf – test line 1) is specific to Pf histidine Rich Protein 2 (HRP 2) of the Plasmodium falciparum species and the other line (PAN – test line 2) consist of a monoclonal antibody specific to PAN plasmodium lactate Dehydrogenase (*p*LDH). The control line (C) consists of Goat anti-Rabbit IgG. The conjugate pad is dispensed with colloidal gold conjugated to P. falciparum specific HRP2, PAN specific *p*LDH antibodies and rabbit IgG. The test is designed for the differential diagnosis between Plasmodium falciparum and the other pan specific species (p. vivax, malariae and ovale).

After addition of the blood sample and the assay buffer to the respective wells on the test containing a strip, the whole blood gets lyses and if the sample contains detectable levels of the Pf HRP2 antigen and / or PAN pLDH antigen it reacts with the respective gold conjugated with malaria Pf specific HRP2 antibodies and/or PAN pLDH specific antibodies to form a complex. The unbound colloidal gold particles along with complex move on to the nitrocellulose membrane. This complex moves further and reacts with the respective malaria Pf specific HRP2 antibodies/PAN specific pLDH antibodies test lines on the nitrocellulose membrane area to form colored bands (Test bands). The unbound complex, unbound gold and the rabbit IgG conjugated colloidal gold particles move further to the goat-anti rabbit IgG coated control area form a colored band (C- Control line). The appearance of test lines and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

MATERIALS PROVIDED

1.Test Device
2.Desiccant
3.Dropper
4. Assay Buffer
5. Product Insert

MATERIALS NEEDED BUT NOT PROVIDED

1.Stopwatch

STORAGE AND STABILITY

1.Store in the sealed pouch in a dry place in between temperature 2°C to 3°C.Do not freeze. The kit is stable within the expiration date printed on the label

2.Once open the pouch the test strip should be used immediately. Prolong exposure to ambient humidity will cause product deterioration.

PRECAUTION

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the C and T lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Do not use if pouch is torn or damaged.
4. Do not open the foil pouch until you are ready to start the test.
5. Keep out of the reach of children.

SPECIMEN COLLECTION

Fresh anti-coagulated whole blood should be used as a test sample. EDTA 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 store the specimen at 2°C to 8°C for up to three days before testing and for long term storage please keep the sample below -20°C. Clotted blood samples should not be used for performing the test. Fresh blood from finger prick/ puncture may also be used as a test specimen.

PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test device, sample dropper and desiccant pouch. Once opened, the device must be used immediately.
3. Label the test device with patient's identity
4. Evely mix the anti-coagulated blood sample by gentle swirling. Dip the sample. Ensuring that a dropper full of blood is retrieved, blot the blood so collected in the sample port "S". (This delivers approximately 5 µl of the whole blood specimen).

OR

In case finger prick blood is being used, touch the sample dropper to the blood on the finger. Ensuring that a dropper full of blood is retrieved , immediately blot the specimen in the sample port "S". (Care should be taken that the blood sample

has not clotted and the transfer to the sample port is immediate).

OR

Alternatively, 5 µl of the anti-coagulated or fingerprick specimen may be delivered in the sample port 'S' using a micropipette.

5. Immediately dispense 2 drops of the Assay Buffer into buffer port 'B', by holding the buffer bottle vertically. (After 5 min add 2 more drops of assay buffer for better background clearance.)
6. Read the results at the end of 20 min.

TEST INTERPRETATION (REFER TO FIGURE)

NEGATIVE for Malaria: Only one purplish pink band appears in the control window 'C.



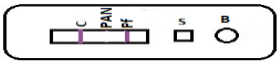
POSITIVE for P. falciparum or mixed infection: In addition to the control band, two purplish pink bands appear at regions 'Pf' and 'PAN' in the test window 'T'



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

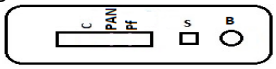


POSITIVE for *P. falciparum*: In addition to the control band, one purplish pink band appears only at region 'Pf' in the test window.



INVALID: The test should be considered invalid if

A) No purplish pink colour line appears in 'C' region 'Pf' and 'PAN' region.



B) No purplish pink colour line appears in 'C' region and line appear in 'pf' and 'PAN' region.



C) No purplish pink colour line appears in 'C' and in 'pf' region and line appear and 'PAN' region.



D) No purplish pink colour line appears in 'C' and in 'PAN' region and line appear and 'pf' region.



LIMITATION

1. The test procedure, precautions, and interpretation of results for this test must be strictly followed.
2. This is only a screening test. All reactive samples must be confirmed with microscopy. As with all diagnostic tests, the test result must always be correlated with clinical finding. The results should be reported only after complying the mentioned procedure.
3. Any modification to the test procedure and/ or use of reagents other than provided with the test kit will lead to invalid and/or false test result

PERFORMANCE CHARACTERISTICS

As per ICMR- National Institute of Malaria Research – New Delhi the sensitivity is 100% and specificity is 100%

SENSITIVITY & SPECIFICITY

	Positive sample	Negative sample	Rate
Positive sample	55	00	98.21% (Sensitivity)
Negative sample	01	14	100% (Specificity)
Total	56	14	98.57% (Total accuracy)

BIBLOGRAPHY

1. Howard, R.J., et al., 1986: Secretion of a Malarial Histidine-rich Protein (Pf. HRPII) from Plasmodium falciparum-infected Erythrocytes'. Cell Biol., 103, 1269-1277
2. Rock, E.P., et al., 1987: Comparative Analysis of the Plasmodium falciparum Histidine-Rich Proteins HRP-I, HRP-II and HRP-III in Malaria Parasites of Diverse Origin. Parasitol., 95, 209-227.
3. Hunte-Cooke A., et al., (1999) Comparison of a Parasite Lactate Dehydrogenase-based Immunochromatographic ® Antigen Detection assay (OptiMAL) with Microscopy for the Detection of Malaria Parasites in Human Blood Samples. Am J.Trop Med 60(2). 173-176.

REF	Catalog No		Attention Caution
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer	Σ	No. of Tests

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