LordsMed Malaria Pf/Pv Antigen Rapid Test

Catalog No.	Pack Size	Specimen Type
MPVLMR01	25 Test Device	WholeBlood
MPVLMR02	50 Test Device	WholeBlood

INTENDED USE

LordsMed Malaria Pf/Pv 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 P. vivax specific pLDH from human whole blood samples. The test may also be used for the differentiation of P. falciparum and P. vivax infection. It is intended for professional use only.

PRINCIPLE

LordsMed Malaria Pf (HRP2)/ Pv (pLDH) Antigen Test utilizes the principle of immuno-chromatography. It contains a membrane strip, which is pre-coated with Monoclonal Anti-HRP II antibody (test line pf) specific to the Histidine Rich Protein-II of P.falciparum and the other with monoclonal Anti pLDH P.vivax antibody (test line Pv) which is specific to the lactate dehydrogenase of P.vivax species. As the test sample flows through the membrane assembly of the device After addition of assay buffer (diluent), the colored colloidal gold conjugates of monoclonal anti-Pv specific pLDH antibody complexes the lysed blood sample. This complex get immobilized on the respective test lines on the nitrocellulose membrane which leads to the formation of pink-purple lines. A line will appear under Pf at the test region in falciparum positive samples, while a line appear under Pv in vivax malaria positive samples. Appearance of line under Pf as well as Pv in the test region suggests a mixed infection. To serve as a procedural control, an additional line of Goat anti-mouse IgG has been immobilized on the strip. If the test is performed correctly, this will result in the formation of pink-purple line on the control line.

MATERIALS PROVIDED

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

MATERIALS NEEDED BUT NOT PROVIDED

1. Stopwatch
2. Lancet

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.

STORAGE & STABILITY

1.Store in the sealed pouch in a dry place in between temperature 2°C to 30°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.

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

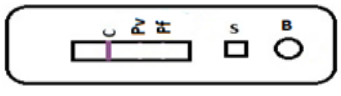
1.Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the device, sample dropper and desiccant pouch. Once opened, the device must be used immediately.
3. Label the test device with patient's identity
4. Prior to testing, open the assay buffer bottle correctly by breaking the seal of the cap and pierce the nozzle by tightly screwing the cap of the bottle.
5. Add 5 µl of whole blood specimen into the sample well (s) using provided sample dropper.

OR

In case finger prick blood is being used, fill up the sample dropper with whole blood specimen upto the mark (5 µl) & add into the sample well.
6. Add 2 drops of the Assay Buffer in the buffer well 'B'. After 5 min of adding specimen & buffer add 1-2 drop of assay buffer for better background clearance.
7. Read the results at the end of 15-20 min.

TEST INTERPRETATION (REFER TO FIGURE)

NEGATIVE : Only one purple band appears in the control window 'C.



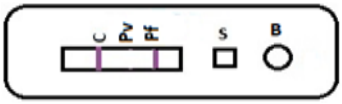
POSITIVE: F**or *P. falciparum* or *P. vivax* :** In addition to the control band, two purple colour bands appear at regions *'Pf'* and *'Pv'* in the test window 'T'



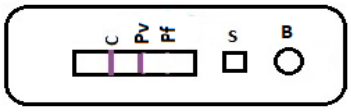
Lord's Mark Industries Ltd., Plot No. A71, Royal Ind. Hub, Poman, Kaman-Bhiwandi Road, Taluka -Vasai, Palghar- 401208, Maharashtra (India). Customer Care No.: 8425982321. Email: ivdcare@lordsmark.com; Website:www.lordsmed.com

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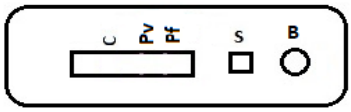
POSITIVE for *P. falciparum*: In addition to the control band, one purple colour band appears only at region '*Pf*' in the test window 'T.



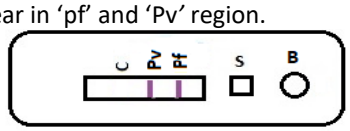
POSITIVE for *P. vivax*: In addition to the control band, one purple band appears only at region 'Pv' in the test window 'T.



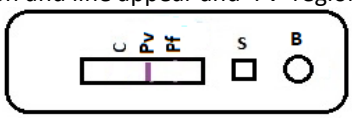
INVALID: The test should be considered invalid if
No purple line appears in 'C' region 'Pf' and '*Pv*' region.



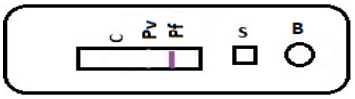
- No purple colour line appears in 'C' region and line appear in 'pf' and 'Pv' region.



- No purple colour line appears in 'C' and in 'pf' region and line appear and 'Pv' region.



- No purple colour line appears in 'C' and in 'Pv' region and line appear and 'pf' region.



PERFORMANCE CHARACTERISTICS

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

AS PER NABL LAB 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)

LIMITATION

1. As with all diagnostic tests the results must always be correlated with clinical findings.
2. The result of the test must be interpreted within the epidemiological, clinical, and therapeutic context. When it seems indicated, the parasitological techniques of reference should be considered (microscopic examination of the thick smear and thin blood films).
3. Any modification to the above procedure and/or use of other reagents will invalidate the test procedure.

BIBLIOGRAPHY

1.David L. Vander Jagt, Lucy A. Hunsaker and John E. Heidrich: Partial Purification and Characterization of Lactate Dehydrogenase from Plasmodium falciparum. Molecular and Biochemical Parasitology, 4 (1981) 255-264
2.World Health Organization- Geneva(2000)New perspectives Malaria diagnosis.

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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