MALARIA Pf/Pv ANTIGEN

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC02

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

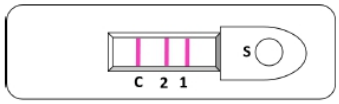
INTENDED USE: Test for qualitative detection of Malaria *P. falciparum* and *P. vivax* in human whole blood samples.

EXPLANATION OF TEST

Malaria is a serious parasitic disease characterized by fever, chills and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds of malaria that can infect humans: Plasmodium falciparum, P. vivax, P. Ovale, and P. Malariae. In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites.

PRINCIPLE

The Malaria Antigen Test contains a membrane strip, which is pre-coated with two monoclonal antibodies as two separate lines across a test strip.



One monoclonal antibody (test line 1) is specific to the P. falciparum histidine rich protein-2 (pf HRP II) and another monoclonal antibody (test line 2) is pan specific to lactate Dehydrogenase (Pan LDH) of plasmodium species (P.Falciparum, Vivax, Malariae, Ovale). Conjugate pad is dispensed with monoclonal antibodies conjugated to the colloidal gold, which are specific to P. Falciparum histidine rich protein-2(pf HRP-II) and pan specific to the Lactate Dehydrogenase (Pan LDH) of other Plasmodium species.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and Instructions For Use.

STORAGE & STABILITY

Store as packaged in the sealed pouch at 2-30 ^{0}C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not freeze.

PRECAUTIONS

1. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
2. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch just before test.
3. Do not mix reagents from different lot.
4. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
5. Follow the testing procedure exactly as mention in the insert.

SPECIMEN COLLECTION AND STORAGE

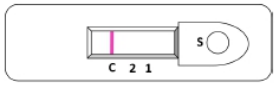
1. Use Blood samples collected from the venipuncture into a collection tube containing EDTA, citrate or heparin.
2. If specimens are not immediately tested, they should be refrigerated at 2-8 °C for upto three days before testing.
3. Anticoagulant such as EDTA, Citrate or Heparin, do not affect the test report.
4. Fresh sample can also be collected using finger-prick method.

TEST PROCEDURE

1. Add 5µl of whole blood into sample well ("S" small well) **(Do not use excess blood)**.
2. Add 3 drops of assay buffer into developer well ("A").
3. Read the test result at 20-25 mins

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:
A pink coloured band appears only at the control region (C), indicating a negative result for Malaria infection.



POSITIVE RESULT:

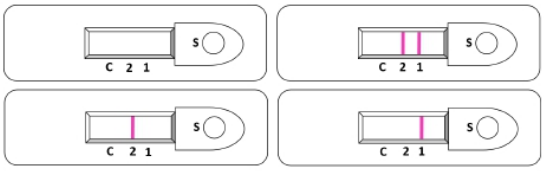
***P. falciparum* Positive:**
The presence of two colour bands (C and 1) indicates a positive result for *P. falciparum*. The pf HRP II present in the sample reacts with the pf HRP II conjugate and move through the test strip where the pf HRP II is captured by the anti –P falciparum specific HRP II.

***P. vivax* and other Plasmodium sp. Positive:**
The presence of two colour bands (C and 2) indicates a positive result for *P. vivax*. The pLDH present in the sample reacts with the other malaria antigen anti-pLDH conjugate and moves through the test strip where the pLDH is captured by pan specific anti-pLDH.

***P. falciparum* and other Plasmodium sp. Positive:**
The presence of 3 coloured bands indicate a positive result for P. falciparum and P Vivax, The pf HRP II present in the sample reacts with the pf HRP II conjugate and move through the test strip where the pf HRP II is captured by the anti *P. falciparum* specific histidine rich protein 2 (pf HRP II) The pLDH present in the sample reacts with the pan anti pLDH conjugate and move through the test strip where the pLDH is captured by pan specific anti pLDH.

INVALID TEST:

No visible band at the control region. Repeat with a new test device.



QUALITY CONTROL

Although the testing device contains an internal quality control (pink coloured band in the control region), good laboratory practice recommends to run a known positive and negative control sample to ensure proper performance. All controls should be handled in the same manner as patient

PERFORMANCE CHARACTERISTICS

The malaria Pf/Pv antigen has been evaluated with positive negative sample Tested by microscopic examination:

	P.f.	Pv
Sensitivity	100%	100%
Specificity	99.80%	

LIMITATIONS

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The test is limited to the detection of antigen of Malaria Plasmodium sp. Although the test is very accurate in detecting pLDH, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

BIBLIOGRAPHY

1. Leonard K. Basco, Frederique Marquet, Michael M. Makler, and Jacques Le Bras: Plasmodium falciparum and Plasmodium vivax: Lactate Dehydrogenase Activity and its Application for in vitro Drug Susceptibility Assay. Experimental Parasitology 80, 260-271 (1995).
2. David L. Vander, Jagt, Lucy A. Hunsaker and John E. Heidrich: Partial Purification and Characterisation of Lactate Dehydrogenase from Plasmodium falciparum. Molecular and Biochemical Parasitology, 4 (1981) 255-264.
3. David J. Bzik, Barbara A, Fox and Kenneth Gonyer: Expression of Plasmodium falciparum Lactate Dehydrogenase in Escherichia coli Molecular and Biochemical Parasitology, 59 (1993) 155-166.
4. Cameron R. Dunn, Mark J. Banfield, John J. Barker, Christopher W. Highm, Kathleen M. Moreton, Dilek Turgut-Balik, R. Leo Brady and J. John Holbrook. The Structure of Lactate Dehydrogenase from Plasmodium falciparum reveals a new target for anti-malarial design. Nature Structural Biology 3(11) 1996, 912-915.
5. Howard, RJ, et al. The secretion of a Malaria Histidine-rich Protein (Pf HRP-2) from Plasmodium falciparum-infected Erythrocytes. J. Cell Biol., (1986) 103, 1269-1277.
6. Rock, EP, et al. Comparative Analysis of Plasmodium falciparum Histidine-Rich Protein - 2, HRP-I, HRP-II, and HRP-III in Malaria Parasitology Diverse Origin. Parasitol., (1987) 95:209-27.
7. Panna, ME, et al. Identification of Plasmodium falciparum Histidine- Rich Protein - 2 in the of Humans with Malaria. J. Clin. Microbiological 29:1629-1634.
8. Rodriguez-del Valle, M. et al, Detecting Antigens and Antibodies in the Urine with Plasmodium falciparum Malaria. Slit Microbiol., (1991) 29:1236-1242.

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

ANAMOL LABORATORIES PVT. LTD.
61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.
Customer Care: +91-9823388695.

admin@anamollabs.com
exports@anamollabs.com
www.anamollabs.com

ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE