ASTAM DIAGNOSTICS

PRODUCT INSERT

REF HCGM

PRATHAM® MALARIA ANTIGEN Pf/Pv TEST DEVICE

For the qualitative and differential detection of Malaria (Pv) pLDH and (Pf) HRP-2 in human whole blood.

INTENDED USE

PRATHAM® One Step Malaria Antigen Pf/Pv Test Device is an in vitro diagnostic rapid test based on the principle of immunochromatography test for qualitative detection of specific antigens of Plasmodium vivax (Pv) pLDH and Plasmodium falciparum (Pf) HRP-2 in human whole blood. For professional use only.

INTRODUCTION

Malaria is caused by four species of Plasmodium: P. falciparum, P. vivax, P. ovale, and P.malariae. The disease results from the multiplication of malaria parasites within red blood cells of the host causing symptoms that typically include fever, headache, joint pain, vomiting, anemia (caused by hemolysis), haemoglobinuria, retinal damage, convulsions, in severe cases progressing to coma, and death. The classic symptom of malaria is sudden coldness followed by rigor and then fever and sweating lasting four to six hour. Of these P. falciparum and P. vivax are considered to be of utmost importance due to incidence of cerebral malaria and drug resistance associated with P. falciparum and high rate of infectivity and relapse associated with P. vivax. As the course of treatment is depended on the species of Plasmodium infection, differentiation between them is of utmost importance. Malaria Pv/Pf antigen test utilizes a pair of anti-plasmodium lactate dehydrogenase (pLDH) specific to Pv and anti-histidine rich protein-II (PfHRP-II) specific to Pf. This enables simultaneous and differential detection Pv and Pf infection in an individual. The test can be performed by minimally skilled personnel without laboratory equipment.

TEST PRINCIPAL

Pratham® One Step Malaria Antigen Pf/Pv Test Device is a two site sandwich immunoassay based on the principle of immunochromatography on a membrane. The test specimen is dispensed into the sample well (S) of the test card followed by sample running buffer in the buffer well (B). The detergent in the buffer lyses red blood cells and releases various plasmodium antigens. Lysed sample flows through the membrane assembly of the card it reacts with antibody-colloidal gold conjugate specific to Pv and or Pf in the conjugate pad. This complex moves further on the membrane to the test region where it is immobilized by the anti P. vivax specific pLDH antibody and or anti P. falciparum HRP-II antibody coated on the membrane leading to formation of colored band (S) which confirms a positive test result. A colored band will appear at the Pv region of the test window if the test is positive for P. vivax infection of it will appear at the Pf region if the test is positive for P. faliciparum infection. Appearance of band in both the regions suggests mixed infection. Absence of colored band in the test region indicates a negative result. The unreacted conjugate and unbound complex moves further on the membrane and it subsequently immobilized by the anti-rabbit IgG antibodies coated on the membrane at the control region 'C', forming a colored band. This control band serves as an internal control to validate the test performance.

KIT COMPONENTS

1. Pouch contents: Test Cassette, Desiccant
2. Assay Buffer
3. Instruction for use
4. Capillary Tube
5. Lancet

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves Micropipette, tips & centrifuge etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of self life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

SPECIMEN COLLECTION AND STORAGE

1. No prior preparation of the patient is required.
2. Collect fresh whole blood specimens by venipuncture or finger prick according to the standard procedure, EDTA or heparin can be used as anticoagulants.
3. Preferably use fresh whole blood samples. If immediate testing is no possible, specimens can be stored at 2-8ºC upto 72 hours before testing. For long storage, freeze at -20ºC or below. Specimens should not be frozen and thawed repeatedly. Maximum of two freeze/thaw cycles are allowed.
4. Clotted or contaminated blood should be used for performing the tests.

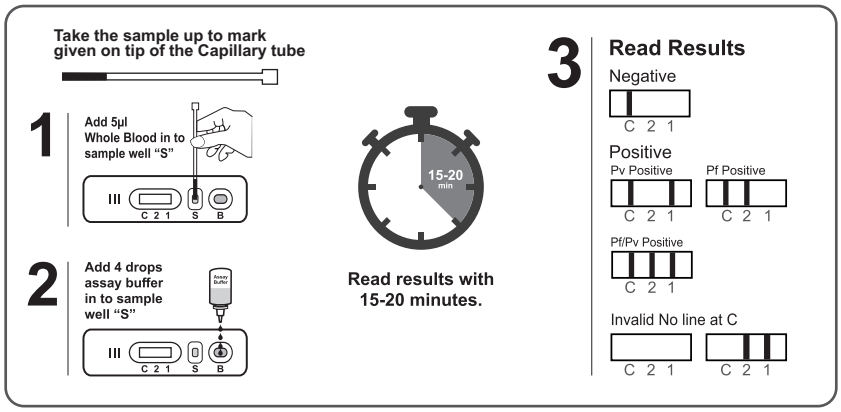
WARNING AND PRECAUTIONS

- For professional use only, not to be used by the general public.
- The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request or registered medical practitioner.
- Bring all reagents and specimen to room temperature before use.
- Do not pipette any material by mouth.
- Use protective clothing and wear gloves when handling samples.
- Use absorbent sheet to cover the working area.
- Immediately clean up any spills with sodium hypochlorite.
- Dispose off all the reagents and material used as if they contain infectious agent.
- Neutralize acid containing waste before adding hypochlorite.
- Do not use kit after the expiry date.
- Do not mix components of one kit with another.
- Sample running 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.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. If color changes then discard the test and use another test.
4. Collect 5 µl of blood using the capillary tube (up to indicated marking).
   Note: For better precision, use micro pipette capable of delivering 5 µl specimen.
5. Add 4 drops of Assay Buffer immediately in the buffer well B.
6. Interpret test results within 15-20 minutes. Don't interpret results after 20 minutes.

TEST PROCEDURE & INTERPRETATION OF RESULTS



Negative:

- Appearance of only one colored band at control line region 'C'. The result should be considered negative.

Positive:

- Appearance of colored bands at '2' &'C' regions indicate that specimen has Pf HRP-II antigen and result is positive for P. falciparum.

- Appearance of colored bands at '1' & 'C' regions indicates that specimen has pLDH antigen and result is positive for P. vivax.
- Appearance of colored bands at '1', '2' & 'C' regions indicates that specimen has both Pf HRP-ll and pLDH antigen and result is positive for P. falciparum and P. vivax mixed infection.

Invalid:

- No visible band at the control region. Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

PERFORMANCE CHARACTERISTICS

Sensitivity: Pratham One Step Malaria Antigen Pf/Pv test device was evaluated in various laboratories for sensitivity. Relative Sensitivity: 100% at 200 parasite per micro liter of whole blood.

Specificity: Normal healthy men and women do not have detectable levels of malaria antigens. Homologous and other potentially interfering substances did not cross react with Malaria Pv/Pf Antigen Test. Relative Specificity: 100%.

LIMITATIONS OF THE TEST

1. The Assay Procedure and the Interpretation of Result sections mus be followed closely. Failure to follow the procedure may lead to inaccurate test results.
2. The Pratham Malaria cassette is limited to the qualitative detection of antibodies to Plasmodium. The intensities of the test lines do not have Pratham correlation with the antibody titers in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-Plasmodium antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with Plasmodium parasites.
4. A negative result can occur if the quantity of the anti-Plasmodium antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of the disease in which a sample is collected.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

BIBLIOGRAPHY OF SUGGESTED READING

1. John, S. M., et al., (1998) Evaluation of Optimal, a dipstick test for the diagnosis of malaria. Ann. Trop. Med. Parasitol., 92, 621-622.
2. Quintana M., et al., (1998) Malaria diagnosis by dipstick assay in a Honduran Population with coendemic Plasmodium falciparum and Plasmodium vivax. Am. J. Trop. Med. Hyg. 59(6) 868-871.

3. Palmer, C. J., (1998) Evaluation of Optimal test for rapid diagnosis of Plasmodium vivax and Plasmodium falciparum. J. ClinMicrobiol. 36(1) 203-206.
4. Moody A., et al., (2000) Performance of the Optimal malaria antigen capture dipstick for malaria diagnosis and treatment monitoring. British Journal of Hematology, 109, 1-5.
5. Rodriguez-del Valle, M., et al, (1991) Detection of Antigens and Antibodies in the Urine of Humans with Plasmodium falciparum Malaria. J. Clin. Microbiol., 29:1236-1242.

SYMBOLS

Read instructions for use	Name of Manufacturer	For single use only
No. of test	Expiry Date of Kit.	Date of manufacturing of IVD Kit
IVD In-vitro diagnostic use	Keep away from Sunlight	REF Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:
ASTAM DIAGNOSTICS PVT. LTD.
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Alwar, Rajasthan-301019 (INDIA)
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