Malaria P.f / Pan Antigen Test Cassette

Instructions For Use

1. INTENDED USE

One-Step Malaria Pf/Pan Antigen (MAL Pf/Pan) Test Cassette is a rapid and convenient immunochromato-graphic assay for the qualitative detection of Plasmodium antigens circulating in the human venous and capillary systems with signs and symptoms of malarial infection. The test targets the histidine-rich protein II (HRPII) antigen specific to Plasmodium falciparum (P.f.) and a pan-malarial antigen, common to all four malaria species capable of infecting humans - P. falciparum, P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.). It is intended to aid in the rapid diagnosis of human malaria infections and to aid in the differential diagnosis of Plasmodium falciparum infections from other less virulent malarial infections. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

2. SUMMARY AND PRINCIPLE OF THE ASSAY

Malaria is one of the most prevalent parasitic diseases across the world. Each year it causes up to 3 million deaths and close to 5 billion cases of clinical illness worldwide. Four species of the Plasmodium parasites are responsible for malaria infections in human: P. falciparum, P.vivax, P.ovale and P.malariae. Of these, P. falciparum and P. vivax are most prevalent. The disease is transmitted by the Anopheles mosquito or in rare cases, by blood transfusion. The parasites mature in hepatocytes and release merozoites into the blood. Merozoites multiply within red blood cells, causing symptoms such as fever, chills, flu-like illness and anemia, and in severe cases, coma and death.

Diagnosis of malaria using traditional microscopy methods can be difficult and requires precise and meticulous microscopy. Thin and thick smears for malaria detection are labor-intensive and require skilled handling with an experienced technologist required for interpretation. Even under ideal conditions, microscopic examination of stained blood smears is less than 100% sensitive. It is important that physicians be aware that empiric treatment is required for P. falciparum if signs and symptoms of individuals warrant immediate therapy.

One-Step Malaria Pf/Pan Test is an antigen-capture immunochromatographic assay, detecting presence of specific soluble proteins, histidine-rich protein II (HRP-II) specific for Plasmodium falciparum and pan-malarial antigen (an antigen shared by all Plasmodium species causing human malaria) in human whole blood samples. HRP-II and pan-malarial antigens are present in, and released from, infected red blood cells in P.f and P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.) infections, respectively. Monoclonal antibodies specifically against pan-malarial antigen and HRP-II are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test lines T1 and T2 of the nitrocellulose membrane. When a blood sample is added, it rehydrates the gold-antibody conjugate and the HRP-II or pan-malarial antigen, if any in the sample, will interact with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T1 and T2) where they will be captured by immobilized antibodies, forming a visible pink line (Test band (T1 and/or T2) indicating a positive result). If HRP-II or pan-malarial antigens are absent in the sample, no pink line will appear in the Test Zone (T1 and T2) indicating a negative result.

To serve as an internal process control, a control band should always appear after the test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

The detection limit of One-Step MAL Pf/Pan is 50 parasite/µl for P. falciparum, and 500 parasite/µl for P. vivax in whole blood sample. Clinical performance have not been adequately established for P. ovale (P.o.) and P. malariae (P.m.).

3. PACKAGE CONTENTS

1) Pouch contents: Test Cassette, desiccant.
2) Assay buffer (6 ml/per bottle) for 25 tests.
3) Test instructions.

4. MATERIALS REQUIRED (BUT NOT PROVIDED)

1) Specimen collection capillary tube, Lancet, Sterile wipe.
2) Clock or timer.

5. WARNINGS AND PRECAUTIONS

1) For professional in vitro diagnostic use only. Do not reuse.
2) Do not use if the pouch seal or its packaging is compromised.
3) Do not use after the expiration date shown on the pouch.
4) Do not mix and interchange different specimens.
5) Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
6) Wash hands thoroughly after finishing the tests.
7) Do not eat, drink or smoke in the area where the specimens or kits are handled.
8) Clean up spills thoroughly with appropriate disinfectants.
9) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
10) Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
11) Keep out of children’s reach.

6. SPECIMEN PREPARATION

1) Samples should be collected aseptically by a fingerstick or venipuncture according to standard methods.
2) Whole blood samples should be used immediately.
3) Use a collection capillary tube to deliver 5 µl samples or collect venous blood into EDTA tube. Use a lancet to puncture the skin and allow a blood droplet to form. Touch the collection capillary tube to the blood droplet and transfer to the test device immediately. To collect venous blood, use the standard venipuncture procedure and collect blood into an EDTA tube.
4) If the test cannot be performed immediately, the blood may be stored for up to three days at 2ºC to 8ºC. Ensure that the blood sample warms to room temperature prior to use.

7. TEST PROCEDURES

1) Remove the testing device from the sealed pouch by tearing at the notch. Place the testing device on a leveled surface.

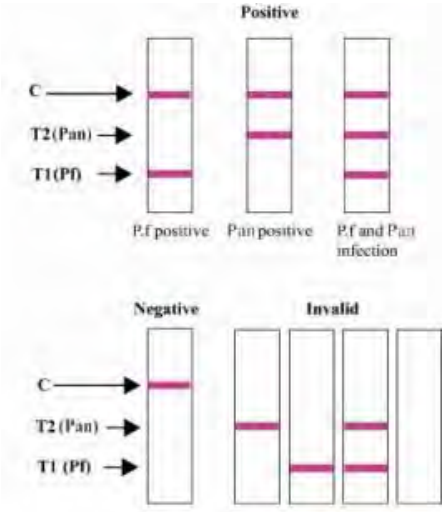
2) Transfer the blood sample (5 µl) from the sample pipette to the Sample Well of the device (close to test window). (Hold the pipette vertically and gently touch the end against the pad within the sample well for transferring).

3) Immediately add four drops (160 µl) of the assay buffer to the Buffer Well (close to the bottom) of the testing device.

4) Read the result in 20-30 minutes. Ensure that the background of the test area has no excess blood before interpreting the result.

Caution: **DO NOT INTERPRET RESULTS AFTER 45 MINUTES**

8. RESULT INTERPRETATIONS



Negative

A pink colored band appears only at the control region (C), indicating a negative result for Malaria P.f and Pan infections.

Positive

P.f positive: Pink bands appear at control region (C) and P.f (T1) test regions, indicating a positive result for Malaria P.f infection.

Pan positive: Pink bands appear at the control region (C) and Pan (T2) test regions, indicating a positive result for P. vivax (P.v.) or P. malariae (P.m.) or P. ovale (P.o.)

P.f and Pan positive: Pink bands appear at the control region (C) , Pan (T2) and P.f (T1) test regions, indicating a mixed infection of P.f. with another species.

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.

9. QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

10. STORAGE AND STABILITY

1) Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
2) The bottle containing the buffer should be stored at 2-30ºC.
3) The test device should be kept away from direct sunlight, moisture and heat.

11. LIMITATIONS

1) Humidity and temperature can adversely affect results.
2) Here is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
3) Although the test demonstrate superior accuracy in detecting HRP-II antigen of P. falciparum, pan-malarial antigen (an antigen shared by all Plasmodium species), a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. 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.

12. Bibliography of suggested reading

1) David R. and et. al. A Longitudinal Study of Type-Specific Antibody Responses to Plasmodium falciparum Merozoite Surface Protein - 1 in an Area of Unstable Malaria in Sudan. Journal of Immunology, 161: 347-359 (1998).
2) Alon Warburg and Imogene Schneider. In Vitro Culture of the Mosquito Stages of Plasmodium falciparum. Experimental Parasitology 76, 121-126 (1993).
3) Helen L.Gibson, Jeffrey E.Tucker: Structure and expression of the gene for Pv200, a major blood-stage surface antigen of Plasmodium vivax. Molecular and Biochemical Parasitology, 50 (1992) 325-334
4) Arthur E.Brown, H.Kyle Webster: Characteristics of Natural Antibody Responses to the Circumsporozoite protein of Plasmodium vivax. Am. J. Trop.Med.Hyg.,44(1), 1991, p.21-27 (90-173)

Manufacturer
ATLAS LINK TECHNOLOGY CO., LTD
Road Xing Min, Guan South Industry Zone, 065500 Langfang City, Hebei Province, CHINA
WEB: https://www.invitro-test.com

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