MALARIA Pv/Pf RAPID TEST

INTENDED USE

Nuvision Malaria Pv/Pf Test is a rapid immunochromatographic assay for the qualitative detection of HRP-II (histidine rich protein II) specific for P.falciparum and pLDH antigen specific to P.vivax of Malaria in human Serum/Plasma/Whole blood samples. It is intended for professional use as a tool in the diagnosis and controlling the treatment of various Malaria infections and also discriminates between *P. falciparum* and *P. vivax.*

SUMMARY

Malaria is one of the most prevalent parasitic diseases across the world. Four species of the Plasmodium parasites are responsible for malaria infections in human, i.e. *P. falciparum, P.vivax, P.ovale and P.malariae*. Of these, *P. falciparum and P. vivax* are the most prevalent. The disease is transmitted by the Anopheles mosquito or in rare cases, by transfusion. The parasites mature in hepatocytes and release merozoites into the blood. Merozoites multiply within red blood cells, inducing symptoms like fever, chills, flu-like illness and anemia, and in severe cases, coma and death.

PRINCIPLE OF THE ASSAY

Nuvision Malaria Pv/Pf Test is an antigen-capture immunochromatographic assay, detecting presence of specific soluble proteins, HRP-II specific for *Plasmodium falciparum* and pLDH for Pv-malarial antigen in human whole blood samples.

Monoclonal antibodies specifically against malarial antigen are conjugated with colloidal gold and deposited on the conjugate pad and also immobilized on the test lines Pv and Pf of the nitrocellulose membrane. When a blood sample is added, it rehydrates the gold-antibody conjugate and the Pf specific HRP-II or Pv-pLDH 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 (Pf and Pv) where they will be captured by immobilized antibodies, forming a visible pink-purple line (Test band Pv and/or Pf) indicating a positive result). If HRP-II or pLDH malarial antigens are absent in the sample, no pink- purple line will appear in the Test Zone (Pv and Pf) 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 Nuvision Malaria Pv/Pf is 50 parasite/µL.

PACKAGE CONTENTS

- **25 Test kits (pouches) per box**
- **Pouch contents: Test Cassette, Desiccant.**
- **5µL inverted cup sample dispenser (25 sticks in one pack)**
- **Buffer Solution (1 vial, 3 mL/vial)**
- **1 Test instruction per box**

MATERIALS REQUIRED (BUT NOT PROVIDED)

- **Clean, specimen collection container.**
- **Clock or timer.**

WARNINGS AND PRECAUTIONS

- **For professional *in vitro* diagnostic use only.**
- **Do not reuse.**
- **Do not use if the product seal or the packaging is compromised.**
- **Do not use, after the expiration date shown on the pouch.**
- **Do not mix and interchange different specimens.**
- **Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.**
- **Wash hands thoroughly after finishing the test.**
- **Do not eat, drink or smoke in the area where the specimens or kits are handled.**
- **Clean up spills thoroughly with appropriate disinfectants.**
- **Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.**
- **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.**
- **Keep out of children's reach.**

SPECIMEN PREPARATION

- **For serum samples, collect blood in a tube without anticoagulant and allow it to clot.**
- **For plasma samples, collect blood in a tube containing anticoagulant.**
- **Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.**
- **Whole blood: whole blood should be collected over heparin, citrate, or EDTA. Mix the blood by inversion and use it to the test. If fingertip blood is used to the test, prick the finger and collect the blood by a capillary tube/Sample dispenser given in the kit. And then, load the blood onto the sample well (S) of the test device.**
- **Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.**
- **The blood may be stored at 2°C to 8°C for up to three days if the tests cannot be performed immediately. Ensure that the blood samples are allowed to attain room temperature prior to use.**

Note: Hemolytic samples should not be used!

PROCEDURE

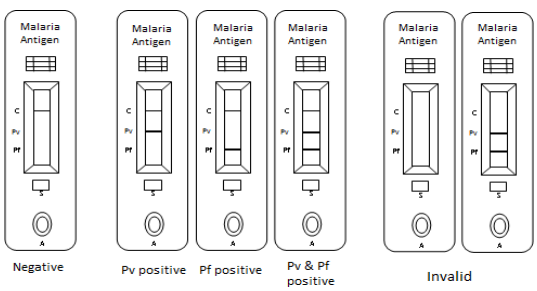
- **Bring the kit components to room temperature before testing.**
- **Open the pouch and remove the Test. Once opened, the test must be used immediately.**
- **Label the test card with patient's identity.**
- **Hold the 5 µL inverted cup sample dispenser, dip into the Specimen to be collected and add that 5 µL of whole blood or serum/plasma into the sample well that is marked with "S" on the testing device. Gently press the stick into the sample well and let the sample dispenser touch on the bottom of sample well and dispense completely.**

- **Add 2 drops (~90µL) of buffer solution in the buffer well "A" (below the sample well).**
- **Read the results at the end of 20 minutes. A strong positive sample may show result earlier.**

Note:

1. **Some positive samples may show positive results before 15 minutes.**
2. **DO NOT READ RESULTS AFTER 30 MINUTES. To avoid confusion, discard the test device after interpreting the results.**

INTERPRETATION OF RESULTS



Negative

A pink-purple colored band appears only at the Control region (C), No band appears in Test region.

Positive

Along with the Control band, if only Pf band appears, the blood sample is infected with P. falciparum. If only the Pv band appears, the blood sample is infected by P. vivax (in usual) and if Control, Pv and Pf all three bands appears the blood sample is infected by P.falciparum and P.vivax.

Invalid

If at 20 minutes, the pink-purple band does not appear in the Control line (C), the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test device.

Note:

Nuvision Malaria Pv/Pf Ag is designed for primary screening test of malaria infection. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.

STORAGE AND STABILITY

- **Test device in the sealed pouch should be stored at 2°- 30°C. Do not freeze the test device.**
- **If stored at 2°-8°C, ensure that the device is brought to room temperature before opening.**
- **The test device should be kept away from direct sunlight, moisture and heat.**
- **Do not expose the kit over 30°C.**

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

Malaria Pv-Pf Samples	Positive	Negative	Total
Pv Positive	32	01	33
Pf Positive	59	01	60
Malaria Negative	03	109	112
Total	94	111	205

Relative Sensitivity (for Pv): 96.97%,
Relative Sensitivity (for Pf): 98.33%,
Relative Specificity: 97.32%, Overall agreement: 97.54%

LIMITATIONS

- **This product is an *in vitro* diagnostic test designed for professional use only.**
- **Humidity and temperature can adversely affect results.**
- **The instructions for the use of the test should be followed during testing procedures.**
- **There 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.**

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