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**“See Now” Malaria P.f / P.v Antigen
 Cassette Test -Whole blood
 For in vitro Diagnosis Use
 Product Code: SN 8.1’**

INTRODUCTION

The “See Now” Malaria pf /pv antigen test is a rapid and convenient immunochromatographic in vitro assay. It is designed for detection of P. falciparum specific histidine rich protein-2 (Pf HRP-2) and Malaria P. vivax specific lactate dehydrogenase (pvLDH) in human blood as an aid in the diagnosis of Malaria infection.

SUMMARY OF THE 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. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year. At the present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood will be put onto a microscope slide and stained so that the parasites will be visible under a microscope.

The „See Now” Malaria pf (HRP II) / pv (LDH) 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-2) and another monoclonal antibody (test line 2) is specific to the lactate dehydrogenase of the P. vivax species (pvLDH). Conjugate pad is dispensed with monoclonal antibodies conjugated to colloidal gold, which are specific to P. falciparum histidine rich protein-2 (Pf HRP-2) and specific to the lactate dehydrogenase of P. vivax. Therefore, the antigen of Plasmodium falciparum and Plasmodium vivax can be differentially detected.

MATERIALS PROVIDED

- Test cassette
- Buffer, plastic pipette
- Instruction of use

SPECIMEN COLLECTION AND STORAGE

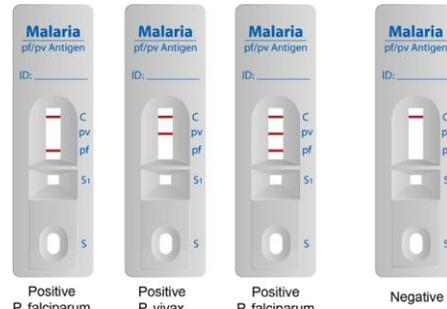
- **Whole Blood specimen**
 Use the tube with EDTA or heparin anticoagulant. Gathered blood from syringe can cause faster hemolytic, and should be avoided. Operate the test within an hour after collecting.
- **Finger puncture whole blood**
 Clean the finger with an alcohol pad and let dry
 Take a lancet and make a quick deep slab on the side of the finger.
 Avoid squeezing the fingertip to accelerate bleeding as this tends to dilute the blood with excess tissue fluid.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Take 5µL of whole blood and drop the specimen into the sample well (S1) ;
- Add 2 drops of buffer (80µL) into insertion well marked S and start the time.
- Read the results at 20 minutes. Ensure that the background of the test area is white before interpreting the result.
- **Positive sample may show positive results within a few minutes after the sample & buffer are added. However, to confirm a negative result, please wait until 20 minutes.**

INTERPRETATION OF RESULTS

Positive



- 1) P. falciparum Positive Reaction**
 The presence of two color bands, “C” and “pf”, indicates a positive result for P. falciparum.
- 2) P. vivax Positive Reaction**
 The presence of two color bands, “C” and “pv” indicates a positive result for P. vivax.

3) P. falciparum and P. vivax Positive Reaction

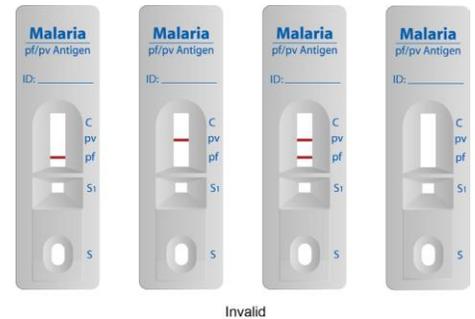
The presence of three color bands indicates a positive result for P. falciparum and P. vivax.

4) Negative

Only one color band appears at the control region.

5) Invalid

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



STORAGE AND STABILITY

The test kit can be stored at temperature (4 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat. DO NOT FREEZE.

PRECAUTION

- FOR IN VITRO DIAGNOSTIC USE ONLY.
- Don't use it after the expiration date.
- The test device should not be reused.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.