Malaria Pf/Pv Antibody Detection Test
(Serum, Plasma, Whole Blood)

INTENDED USE:
Malaria Pf/Pv test is an immunochromatographic (rapid) test for the qualitative detection of antibodies of all isotopes (IgG, IgM, IgA) specific to *Plasmodium falciparum* and *Plasmodium vivax* simultaneously in human serum, plasma or whole blood.

INTRODUCTION:
Malaria is a serious parasitic disease characterized by fever, chills and anaemia 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 present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood will be put into a microscope slide and stained so that the parasites will be visible under a microscope.

PRINCIPLE:
Malaria Pf/Pv test contains a membrane strip, pre-coated with recombinant malaria Pf capture antigen (MSP, CSP) on test band 1 region and with recombinant malaria Pv antigen (MSP, CSP) on test band 2 region. The recombinant malaria Pf/Pv antigen (MSP, CSP) - colloidal gold conjugate and serum sample moves along the membrane chromatographically to the test regions (1,2) and forms a visible line as the antigen-antibody-antigen gold particle complex forms with high degree of sensitivity and specificity.

PRECAUTIONS:
- For professional in-vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

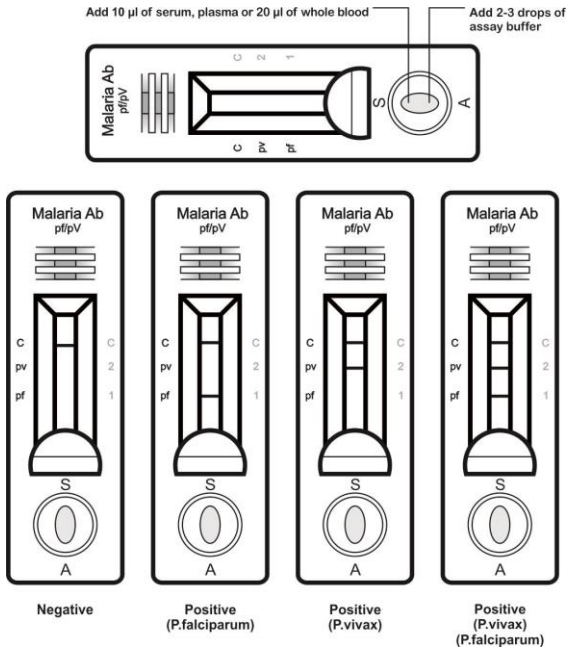
STORAGE & STABILITY:
The kit can be stored at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

PRESENTATION:
Materials Provided :
- Test Device
- Assay Buffer
- Package Insert
- 10 µl Dropper (Inside the test device pouch)

Materials Not Provided:
- Pipette
- Timer

SPECIMEN COLLECTION & PREPARATION
(Collection by venipuncture)
1. Collect whole blood into a collection tube containing EDTA, citrate or heparin by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2-8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen after long-term storage more than three days can cause non-specific reaction.
3. When stored at 2-8°C, the whole blood sample should be used within three days.

Direction for Use:



TEST PROCEDURE:
1. Add 10µl (1 drop) of serum / plasma or 20µl (2 drops) of whole blood to the sample well "S".
2. Add 2-3 drops of the assay buffer.
3. Interpret test results in 5 to 20 minutes. Do not interpret test result after 20 minutes.

INTERPRETATION OF RESULTS:
1. ***P. falciparum*** **Positive reaction**
   The presence of a color band at 1 & C indicates a positive result for *P. falciparum*. The antibody present in the sample reacts with the CSP, MSP conjugate and moves through the test strip where the antibody is captured by both *P. falciparum* specific CSP, MSP antigens.
2. ***P. vivax*** **Positive reaction**
   The presence of a color band at 2 & C indicates a positive result for P. vivax. The antibody present in the sample reacts with the CSP, MSP conjugate and moves through the test strip where the antibody is captured by both the *P. vivax* specific CSP, MSP antigens.

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3. **Negative reaction**
   The presence of only one band at the C indicates a negative result.
4. **Invalid**
   The test is invalid if the C line does not appear. If this occurs, the test should be repeated using a new cassette.

As no true standards have been established for determining the absence or presence of Malaria (P. falciparum) in whole blood specimens, it is recommended that the performance of the kit should be compared to established panels or reference materials if found available.

LIMITATIONS:

The test is limited to the detection of antibodies to Malaria both *Plasmodium falciparum* and *Plasmodium Vivax* simultaneously. Although the test is very accurate in detecting antibodies to Malaria Pf/Pv, 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.

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