Malaria pf/pv(MSP) Antibody Rapid Test

For detection of Malaria antigens in Serum/Plasma/Whole Blood.

Introduction

Malaria is one of the most serious and complex health problems facing humanity. Malaria is considered sometimes fatal parasitic disease characterized by fever, chills and anemia, which can be transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds of malaria that can affect humans namely *Plasmodium Falciparum, P. Vivax , P. Ovale, and P. Malariae*, out of which *P. Falciparum* is most predominant followed by *P. Vivax*. In human, the parasite called sporozoites migrate to the liver where they mature and release another form, the merozoites. Over two billion people live in malaria-affected areas in the tropics and sub-tropics and each year approximately 300 million infections occur, resulting in up to 3 million deaths according to a report from World Health Organization.

The definite diagnosis of Plasmodium Falciparum (Pf) malaria continues to be cased on clinical criteria supported by microscopic examination of whole blood. However, Microscopy is time consuming, labor intensive, expensive and requires considerable technical skills and hence the Rapid test is considerably becoming popular and supportive in the diagnosis of malaria disease.

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

Intended Use

For the rapid qualitative determination of Malaria pf/pv antibody in human blood as an aid in the diagnosis of Malaria infection

Materials Included and Active Ingredients

1) Malaria pf/pv Ab kit contains the following items to perform the assay.
   - Malaria pf/pv Ab test device foil pouched with a desiccant
   - Assay Buffer
   - Instruction for use

Kit Precautions and Storage Instructions

1) For best results, adhere to instructions provided
2) All specimens should be handled as potentially infectious
3) The test device should be stored at room temperature
4) The test device is sensitive to humidity as well as heat
5) Do not use beyond expiration date
6) Do not use test kit if pouch is damaged or seal is broken
7) Use test device immediately after removing from the pouch
8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.

Warnings

1) For in vitro diagnostic use only. DO NOT RE-USE test device
2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
3) Do not eat or smoke while handling specimens
4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5) Avoid splashing or aerosol formation
6) Clean up spills thoroughly using an appropriate disinfectant
7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
8) Do not mix with other specimens.

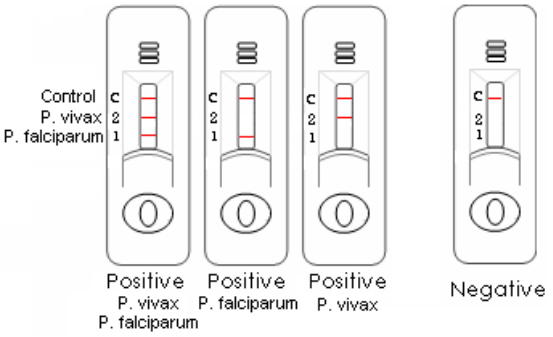
Specimen Collection, Storage and Precautions

1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant
2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
3) Whole Blood (WB): Collect WB with a lancing device. WB specimen can be delivered to test card directly. Or if applicable, collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture. Optimal results were obtained when patient samples were tested immediately after collection. Whole blood samples should be used within 24 hours after collection
4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8 ^{o}C. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30 ^{o}C) prior to use.
5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

Test Procedure

1) Allow all test components and specimen to come to room temperature prior to testing
2) Remove the test device from the foil pouch, and place it on a flat, dry surface
3) With a micropipette (not provided) or a disposable dropper, add about 10 µL serum/plasma or 20 µL whole blood specimen into the sample well marked “S”
4) Add one drop (40 µL) of assay buffer into developer well
5) As the test begins to work, you will see red color move across the result window in the center of the test device.
6) Interpret test results at 15-20 minutes. Caution: Do not read test results after 30 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)

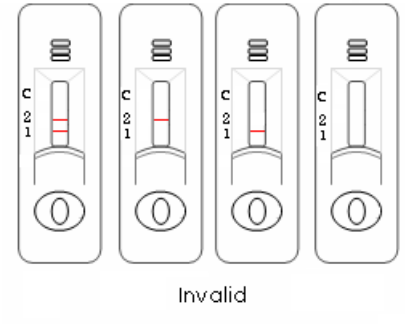


1) P. falciparum Positive reaction
The presence of a color band at the 1 indicates a positive result for *P. falciparum*.

2) P. vivax Positive reaction
The presence of a color band at the 2 indicates a positive result for *P. vivax*.

4) Negative reaction
The presence of only one band within the result window indicates a negative result.

5) Invalid
The test is invalid if the control line does not appear. If this occurs, the test should be repeated using a new strip



Limitations of the Test

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.

Suggested Readings

1. Gilles HM: Management of Severe and Complicated Malaria. A Practical Handbook. WHO, 1991.
2. Goldsmith RS, Heyneman D: Tropical Medicine and Parasitology. Appleton & Lange, 1989.
3. Price DL: Procedure Manual for the Diagnosis of Intestinal Parasites. CRC Press, 1994.
4. Voller A: Immunoassays for Tropical Parasitic Infections. Trans R Soc Trop Med Hyg 1993;87:497
5. World Health Organization: WHO Expert Committee on Malaria, 20th Report. WHO Tech Report Series 892. WHO, 2000.

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