



Malaria Antibody Test Cassette
Serum/Plasma or Whole Blood

Not for sale in USA

Intended Use

For the rapid qualitative determination of antibodies to Malaria circumsporozoite protein (CSP) and major merozoite surface protein (MSP) in human blood as an aid in the diagnosis of Malaria infection.

Summary

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 parasites 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 definitive diagnosis of Plasmodium Falciparum (Pf) malaria continues to be based 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 isotypes (IgG, IgM, IgA) specific to *Plasmodium falciparum* and *Plasmodium vivax* in human serum, plasma or whole blood. This is a "3rd generation" method using in-direct binding principle with double sandwich antigen (Ag-Ab-Ag). The ABI Malaria Pf/Pv test contains a membrane strip, which is pre-coated with recombinant malaria P.f. capture antigen (MSP, CSP) on test band 1 region and with recombinant malaria P.v. antigen (MSP, CSP) on test band 2 region. The recombinant malaria Pf/Pv antigen MSP, CSP – 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.

Test Performance

Sensitivity: 97.8% (with International Standard Reference Panels of WHO and Sigma QC Panels)

Specificity: 99.8%. No cross reactivity with *P. Malariae*, *P. Ovale*, Dengue fever, *Giardia Lamblia*, *Trypanosoma*, *Entamoeba Histolytica*.

Materials Provided

- Test Device
- Assay Buffer
- Package Insert
- Materials Not Provided:
- Pipette
- Timer

Storage and Stability

The kit can be stored at room temperature or refrigerated (2-30°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.

Precautions

1. For *in vitro* diagnostic use only.
2. Use disposable gloves while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards.
3. Do not use product after the expiration date.
4. Do not eat or smoke while handling specimens.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Humidity and high temperature can adversely affect results.

Specimen Collection and Storage

Collection by venipuncture

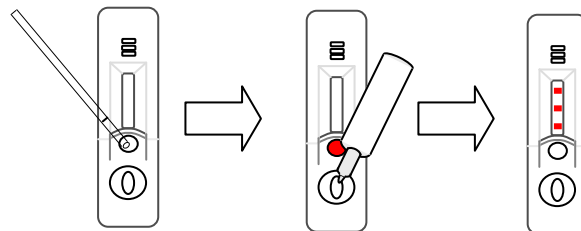
1. Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2-8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen in the long-term keeping 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.

Collection using a lancet

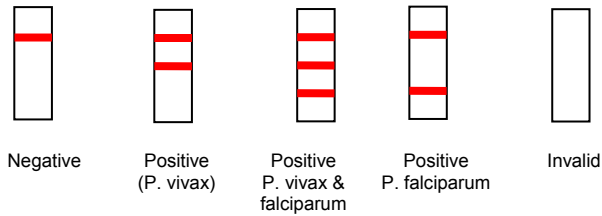
1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet provided.
3. Wipe away the first drop of blood with sterile gauze or cotton.
4. Using the dropper provided, while gently squeezing the tube, immerse the open tip in the blood drop then gently release the pressure to draw blood into the tube.

Test Procedure

Dispense 10 µl of whole blood or 20 µl serum to the (sample port of the cassette as shown).
Add 1 drop of assay buffer to the sample port as shown below.
Read the test results after 30 minutes.



Interpretation of Test Results



1) *P. falciparum* Positive reaction

The presence of a color band at the 1 indicates a positive result for *P. falciparum*. The pLDH present in the sample reacts with the pan anti-pLDH conjugate and moves through the test strip where the pLDH is captured by both *P. falciparum*-specific anti-pLDH and pan specific anti-pLDH.

2) *P. vivax* or other *Plasmodium* sp. Positive reaction

The presence of a color band at the 2 indicates a positive result for *P. vivax* or other *Plasmodium* sp. The pLDH present in the sample reacts with the pan anti-pLDH antibody conjugate and moves through the test strip where the pLDH is captured by pan specific anti-pLDH.

3) Negative reaction

The presence of only one band at the C indicates a negative result.

4) Invalid result

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

PERFORMANCE CHARACTERISTICS

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 be compared to established panels or reference materials if found available. However, Comparative Studies conducted at the Center for Disease Control (CDC) for tropical diseases against microscopic examination of whole blood reported that the ABI Malaria pf/pv Test demonstrated 96.8% and 98.2% sensitivity and specificity, respectively.

AND INTERFERENCE STUDY

To determine the specificity of Malaria test, an in-house study was conducted with 3 separate lots of the Malaria Test to serum with triglyceride concentration up to 500 mg/ml, serum with bilirubin concentration up to 10 mg/100 ml, prostatic acid phosphatase with concentration up to 1000 mIU/ml, and albumin with concentration up to 20 mg/ml. All of the above were analyzed and did not demonstrate interference or cross reactivity with the test.

LIMITATIONS

The test is limited to the detection of antibodies to *Plasmodium falciparum* and *Plasmodium vivax*. Although the test is very accurate in detecting antibodies to Malaria P.f/P.v, 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.

Bibliography

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.

American Bionostica, Inc.
Swedesboro, NJ 08085
Tel: 856-467-7070
info@americanbionostica.com