Tell Me Fast™ Malaria Pf/Pv (CSP/MSP) Antibody Detection Test Device (Serum/Plasma/Whole Blood) Instructions for Use Catalog Number: B704C

Intended Use

For the rapid qualitative determination of Malaria pf/pv antibody 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 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.

Tell Me Fast 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 TELL ME FAST 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.

Technical Specification

Principle: 3rd Generation Method using in-direct binding principle with double sandwich antibody (Ab-Ag-Ab)
Specimen: Serum/Plasma or Whole Blood
Capture Ag: Recombinant P.f Ag (MSP-1, MSP-2, CSP) and Recombinant P.v Ag (MSP, CSP)

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 (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.

Materials

Materials Provided:

- Test Device
- Assay Buffer
- Instructions for Use

Materials Required but 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 of 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.

Directions for Use:

Allow test device, buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Add 10 µL of serum, plasma, or 20 µl of whole blood to the sample well “S”.

2. Add 1 drop (50 µL) of the assay chase buffer to the sample well.

3. Interpret test results in 10 to 20 minutes.

NOTE: Do not interpret test result after 30 minutes.

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Manufactured by: Biocan Diagnostics Inc 160 Suite 309 North Vancouver BC Canada
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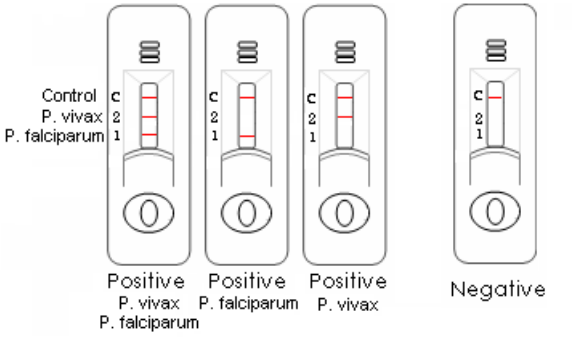
Interpretation of Results:

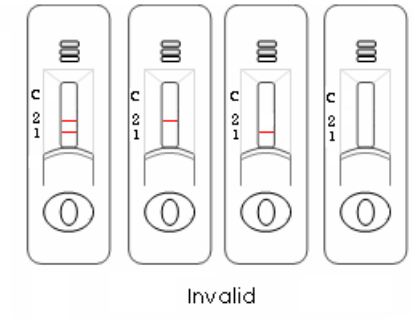
1) P. falciparum **Positive reaction**
The presence of a color band at the 1 indicates a positive result for *P. falciparum*.

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



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 strip.



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.

References

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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