One Step Malaria Anti-P.f/P.v Cassette Test

Revised on 01/2007

1. Introduction

Malaria is a serious, sometimes fatal, 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 human, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites. The disease is a major health problem in much of the tropics and subtropics. More than 200 million people in the world have malaria.

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. At the most recent, clinical diagnostic issues related to malaria are the detection of malaria antibodies in human blood or serum by immunoassay. The ELISA format and immunochromatographic format (rapid test) to detect antibody of malaria are available recently.

2. Intended Use:

IND diagnostic One Step Malaria Anti-P.f/P.v Test is a immunochromatographic (rapid) test for the qualitative detection of antibodies of all isotypes (IgG, IgM, fgA) specific to Plasmodium falciparum and Plasmodium vivax simultaneously in human serum, plasma or whole blood. IND diagnostic One Step Malaria Anti-P.f/P.v Test is intended for professional initial screening use. Any malaria positive specimen screened by this kit should be confirmed by microscopic examination. This kit is for in vitro diagnostic use only.

3. Principle:

IND diagnostic One Step Malaria Anti-P.f/P.v Test is based on the principle of double antigen sandiwich immunoassay for determination of antibodies to Malaria p.v and p.f in whole blood/ serum and plasma samples. Recombinant malaria P.f capture antigens (MSP) and recombinant malaria P.v capture antigens (MSP) are employed to identify anti-Malaria P.f and P.v specifically. This one step test is very sensitive and only takes 20-30 minutes for the result to be read. Test results are read visually without any instrument.

4. Precautions

1) The IND Diagnosticalaria P.f/P.v test devices should be stored at room temperature.

2) The test device is sensitive to humidity and as well as to heat.

3) Perform the test immediately after removing the test device from the foil pouch.

4) Do not use it beyond the expiration.

5) The shelf-life of the kit is as indicated on the outer package.

6) Do not use the test kit if the pouch is damaged or the seal is broken.

5. Specimen collection and Storage

5.1 Whole Blood:

5.1.1 Collect the whole blood using the suitable anti-coagulant.

5.1.2 The whole blood may be used for testing immediately or may be stored at 2 - 8 'C up to three days.

5.2 Serum or Plasma

5.2.1 Centrifuge whole blood to obtain plasma or serum specimen.

5.2.2 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.

5.2.3 Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

6. Precaution:

(1) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.

(2) As known relevant interference: haemolytic samples, rheumatoid factors-contained samples and lipaermic, icteric samples can lead to impair the test results.

(3) Use separate disposable pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.

7. Warnings

1) For in vitro diagnostic use only. DO NOT RE-USE: test device.

2) The instruction must be followed exactly to get accurate results. Anyone performing an assay with this product must be trained in its use and must be experienced in 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 and interchange different specimen.

9) Care should be taken to avoid contamination of the end of bottle when dropping of assay diluents into sample well.

8. Test Procedure:

1) Remove the test device from the foil pouch, and place it on a flat, dry surface.

2) Add the specimen 10 µl of serum or plasma (or 20 µl of whole blood) to the sample well (S) of the test device, then add 3 - 4 drops of assay diluent (approximately 110 µl) and start the timer.

3) As the test begins to work, you will see purple color move across the result window in the center of the test device.

4) Interpret test results at 5 - 20 minutes. A positive result will not change once it has been established at 20 minutes. However, in order to prevent any incorrect results, the result should not be interpreted after 20 minutes.

5) Especially, when you use the whole blood. please interpret the test results within 10 minutes. In this case, do not interpret after 10 minutes.

9. Interpretation of the test

Negative Result
The presence of only one band within tile result window indicates a negative result.

Positive Result

I. Malaria P.f
II Malaria P.v
The presence of not less than two color bands ("I", "II" and "C") within the result window, no matter which band appears first, indicates a positive result for p.f or / and P.v, respectively.

Invalid Result No visible band at all or no colored line appears in the control region. Repeat the test with a new kit.

10. Limitation of the test

1) IND diagnostic One Step Malaria Anti-P.f/P.v Test will only indicate the presence of antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Malaria Plsmodium falciparum vivax infection.

2) 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.

31 If the test result is negative and clinical symptom is persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility Of Malaria Plasmodium falciparum, Malaria Plasmodium vivax infection.

11. Internal Quality Control

The colored band must appear in the control region of the membrane with each test kit, which will indicate proper performance and reagent reactivity.

12. Bibliography of suggested reading

1) David R. and et. al. A Longitudinal Study of Type-Specific Antibody Response, to Plasmodium falciparum Merozoite Surface protein 1 in an Area of Unstable Malaria in Sudan. Journal immunology, 161 : 347-359 (1998).

2) Alon Warburg and Imogene Schneider. In Vitro Culture Of the Mosquito Stage of Plasmodium falciparum. Experimental Parasitology *76, 121- 126* (1993).

3) Helen L.Gibson, Jeffrey E.Tucker : Structure and expression of the gene for Pv200, a major blood-stage surface antigen of Plasmodium vivax.. Molecular and Biochemical Parasitology, 50 (1992) 325-334

4) Arthur E.Brown, H.Kvle Webster: Characteristics of Natural Antibody Responses to the Circumsporozoite protein of Plasmodium vivax.Am. J. Trop. Med. Hyg., 44(1), 1991, p.21-27 (90-173)