One Step Malaria Anti-P.f/P.v Whole Blood/Serum Test

04/2008

INTRODUCTION

The One Step Malaria Anti-P.f/P.v Whole blood/Serum test is a immunochromatographic test for the qualitative detection of antibodies of all isotypes (IgG+IgM+IgA) specific to *Plasmodium Falciparum (p.f)* and *Plasmodium vivax (p.v)* simultaneously in human whole blood, serum or plasma. It is intended for professional use, only for an initial screening test and malaria antibody positive samples should be confirmed by a supplemental assay such a leading commercial malaria antibody detection ELISA or IFA. Finally, malaria positive specimen by this kit should be confirmed by microscopic examination. This kit is for in vitro diagnostic use only.

PRINCIPLE OF PROCEDURE

The One Step Malaria Anti-P.f/P.v Whole Blood/Serum test is a three line-lateral flow chromatographic immunoassay. It is composed of a nitrocellulose membrane pre-coated with recombinant malaria P.f capture antigen (MSP) on test band region 1 and with recombinant malaria P.v capture antigen (MSP) on test band region 2. The recombinant malaria P.f/P.v antigen(MSP)-colloid gold conjugate and 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. This test device has a letter of 1, 2 and C as “Test band 1”, “Test band 2” and “Control Band “on the surface of the test device. Both the test and control bands in result window are not visible before applying any samples. The control band is used for procedural control. Control band should always appear if the test procedure is performed properly and the test reagents of control band are working. Absence of any band in the test regions suggests a negative result.

Materials provided

a) One cassette test device.
b) One pipette dropper per test device
c) desiccant within the test pouch
d) diluents bottle

SPECIMEN COLLECTION & PREPARATION

The One Step Malaria Anti-P.f/P.v whole blood/serum test can be run on serum/plasma/whole blood samples. The test works best on fresh samples. For serum collection, collect blood into a container *without anticoagulant.* Allow the blood to clot and separate the serum from the clot. Use the serum for testing. For plasma/whole blood, collect blood into a container *with anticoagulant*. Use the plasma/whole blood for testing.

If the specimen cannot be tested on the day of collection, store the serum/plasma specimen in a refrigerator (at 2 to 4°C) for up to 3 days. If testing cannot be done within 3 days, serum/plasma should be stored in a freezer (at -20°C or colder). DO NOT store whole blood in freezer. Make sure to stir and bring the serum/plasma/whole blood specimen to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

Attention: human source specimens and all materials coming in contact with them should be handed and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

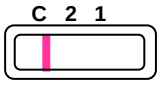
ASSAY PROCEDURE

1. Bring the sample and test components to room temperature if refrigerated.
   Mix the frozen sample (whole blood/serum/plasma only) well prior to assay after it is completely thawed.
2. When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.
3. Label the device with specimen’s ID
4. Transfer **one drop** (20µL) of specimen with the pipette dropper provided to the sample well, and then add **three drops** (90 µL) of diluents buffer from the diluents bottle provided into the sample well immediately. Start the timer.
5. Read the test result in 5~20 minutes after adding the specimen.
6. Don’t read result after 20 minutes.

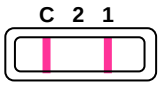
INTERPRETATION OF RESULTS

1. A color band will appear in the left section of the result window to show that the test is working properly. This band is the Control Band.
2. The right section of the result window indicates the test results. If another color band appears in the right section of the result window, this band is the Test Bands.

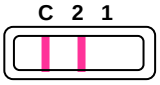
NEGATIVE RESULT:
The presence of only one band within the result window indicates a negative result.



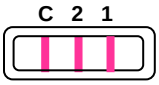
POSITIVE RESULT:
The presence of not less than two color bands (1, 2, and C) within the result window, no matter which band appears first, indicates a positive result for P.f or P.v, respectively.



*** P.f-positive**

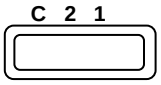


*** P.v-positive**



*** P.f / P.v-positive**

INVALID:
If no C line develops the assay is invalid. In this case, repeat the assay with a new test device.



RECAUTION

1. In vitro diagnostic use only. Do not re-use the test device.
2. Do not use beyond expiration day.
3. Wear protective gloves while handling specimens.
4. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
5. Do not mix and interchange different specimen.
6. Care should be taken to avoid contamination of the end of bottle when dropping of diluents into the sample well.
7. The test strip is moisture sensitive and should be used immediately after taking out of the pouch.

STORAGE AND STABILITY

- ✧ Store the test kit at room temperature (2-30ºC).
- ✧ Each device may be used until the expiration date printed on the label if it remains sealed in the foil pouch containing desiccant.
- ✧ Do not use the test kit if the pouch is damaged or the seal is broken.
- ✧ Do not freeze the kit and or expose the kit to the temperature over 30ºC.

LIMITATION OF THE TEST

1. The One Step Malaria Anti-P.f/P.v whole blood/serum 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 Plasmodium falciparum, Malaria Plasmodium 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 made by the physician after all clinical and laboratory finding s have been evaluated.
3. If the test result is negative and clinical symptom is persisting, 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.

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