Malaria P.f / P.v Antibody Test Cassette

1. Explanation of the test

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 humans, 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) to detect antibody of malaria are available recently.

The Malaria P.f/P.v test is a immunochromatographic (rapid) test for the qualitative detection of antibodies of all isotypes (IgG, IgM, IgA) specific to *Plasmodium falciparum* and *Plasmodium vivax* simultaneously in human serum or plasma.

The Malaria P.f/P.v 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 capture antigen (MSP, CSP) on test band 2 region. The recombinant malaria P.f/P.v 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. This test device has a letter of 1, 2 and C as "Test Line 1", "Test Line 2" and "Control Line" on the surface of the case. Both the Test Lines and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

2. Materials provided

The Malaria P.f/P.v test kit contains following items to perform the assay.

1) The Malaria P.f/P.v test device
2) Assay Diluent (4 ml/bottle)
3) Instructions for use

3. Precautions

The Malaria P.f/P.v test devices should be stored at room temperature. The test device is sensitive to humidity and as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

4. Specimen collection and storage

1) [serum or plasma] Centrifuge whole blood to get plasma or serum specimen.
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.
3) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

5. Warnings

1) For in vitro diagnostic use only.
2) Do not eat or smoke while handling specimens.
3) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4) Avoid splashing or aerosol formation.
5) Clean up spills thoroughly using an appropriate disinfectant.
6) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7) Do not use the test kit if the pouch is damaged or the seal is broken.

6. Procedure

1) Remove the testing device from the sealed pouch by tearing at the notch. Place the testing device on a leveled surface.
2) Transfer specimen (10 μl) from sample pipette to sample well of the device (close to test window). (Hold the pipette vertically and gently touch the end against the pad within the sample well for transferring).
3) Immediately add two drops (80 μl) of the assay diluent to the lower well of the testing device.
4) Read the result in 20-30 minutes. Ensure that the background of the teat area is white before interpreting the result. Do not interpret results after 45 minutes.

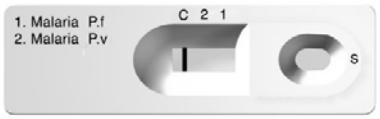
Caution: The above interpreting time is based on reading the test results at room temperature of 15 ~ 30°C. If your room temperature is significantly lower than 15°C, then the interpreting time should be properly increased.

7. Interpretation of the test

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 Band 1 of P.f or / and Test band 2 of P.v.

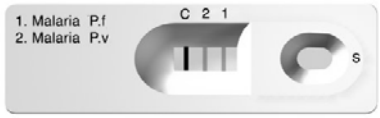
Negative result

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



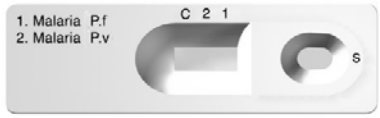
Positive result

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 / and P.v, respectively.



Invalid result

If the purple color band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



8. 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 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.

9. Performance Characteristics

1) Sensitivity and Specificity: The Malaria P.f/P.v test have tested with positive and negative clinical samples tested by microscopic examination of serum.

(1) Malaria P.f evaluation results

Reference		Malaria P.f/P.v rapid test			Total Results
Method	Result	Positive (T1)	Positive (T2)	Negative	
microscopic examination	P.f Positive	150	0	20	170
	P.f Negative	3	0	197	200
Total Results		153	0	217	370

In a comparison of the Malaria P.f/P.v test versus microscopic examination of serum, results gave sensitivity of 88.2% (150/170), a specificity of 98.5% (197/200), and a total agreement of 93.8% (347/370).

(2) Malaria P.v evaluation results

Reference		Malaria P.f/P.v rapid test			Total Results
Method	Result	Positive (T1)	Positive (T2)	Negative	
microscopic examination	P.v Positive	0	158	15	173
	P.v Negative	0	3	205	208
Total Results		0	0	220	381

In a comparison of the Malaria P.f/P.v test versus microscopic examination of serum, results gave sensitivity of 91.3% (158/173), a specificity of 98.5% (205/208), and a total agreement of 95.3% (363/381).

2) Precision

(1) Within run precision was determined by using 10 replicates of four different specimens containing different concentrations of antibody. The negative and positive values were correctly identified 100% of the time.

(2) Between run precision was determined by using the four different specimens containing different concentrations of antibody in 3 different replicates with 3 different lots of test devices. Again negative and positive results were observed 100% of the time.

10. Bibliography of suggested reading

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

2) Alon Warburg and Imogene Schneider. In Vitro Culture of the Mosquito Stages *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.Kyle 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)

Manufacturer

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