

# Health-Chem Diagnostics, LLC

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## ONE STEP™ MALARIA PF/PV CASSETTE TEST - ANTIBODY DETECTION - (SERUM, PLASMA OR WHOLE BLOOD)

### Explanation of the Test

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 the World Health Organization.

The definite 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) Cassette 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* simultaneously in human serum, plasma or whole blood. The Malaria Pf/Pv Cassette 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 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 a high degree of sensitivity and specificity.

### Technical Specifications

Intended Purpose: Immunochromatographic test designed for qualitative determination of Malaria Pv & Pf in serum/plasma or whole blood.

Production Principle: 3rd Generation Method using in-direct binding principle with double sandwich antibody (Ab-Ag-Ab)

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

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

Specimen: Serum/Plasma or Whole Blood

Capture Ab: Recombinant P.f Ag (MSP-1, MSP-2, CSP) and Recombinant P.v Ag (MSP, CSP)

### Materials Provided

The Malaria Cassette Test kit contains the following items to perform the assay:

1. Malaria test cassette.
2. Assay Diluent
3. Instruction

### Precautions

The Malaria Cassette Test devices should be stored at room temperature. The test device is sensitive to humidity 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 date.

### Specimen Collection and Storage

1. The test should be performed using human serum, plasma or whole blood only.
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.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

### 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.

## Test Procedure

1. Remove the test device from its foil pouch.
2. Slowly add 10 µl of serum, plasma, or 20 µl of whole blood to the sample well and then add 3 drops of the assay diluent.
3. Interpret test results in 10 to 20 minutes. Do not interpret test result after 30 minutes.

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

## Interpretation of the Test

1. A color band will appear in the C-section of the Result Window to show that the test is working properly. This band is the Control Band.
2. The T-section of the Result Window indicates the test results. **These bands are Pf (shown as band 1) further from the Control Line (C) and Pv (band 2) for the line next to the C-Line as shown on the diagram below**

### Positive Result:

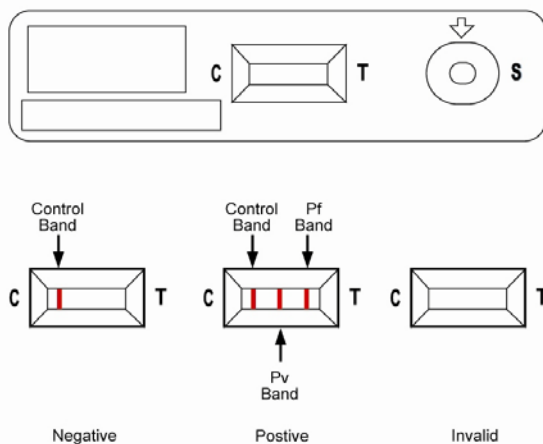
The presence of two color bands within the Result Window regardless of which band appears first indicates a positive result. However, if three bands are present, then pf and pv are both positive, as indicated on the diagram.

### Negative Result:

The presence of only one purple color band within the Result Window indicates a negative result.

### Invalid Result:

If after performing the test no band is visible within the Result Window, 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.



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.

## Performance Characteristics Comparison and Sensitivity Studies

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 Malaria pf/pv Test has 96.8% and 98.2% sensitivity and specificity respectively

## Specificity and Interference Study

To determine the Specificity of Malaria test, an in-house study is conducted with 3 separated lots of the Malaria specimen Test to Serum with triglyceride concentration up to 500 mg/ml, Serum with Bilirubin concentration up to 10 mg/100ml, Prostatic acid phosphatase with concentration up to 1000 mIU/ml, Albumin with concentration up to 20 mg/ml.

All of the above were analyzed and did not show interference or cross reactivity with the test.

## References

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6. World Health Organization: WHO Expert Committee on Malaria, 20<sup>th</sup> Report. WHO Tech Report Series 892. WHO, 2000.

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 Website: [www.healthchemdiagnostics.com](http://www.healthchemdiagnostics.com)  
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## LIMITATIONS OF THE TEST

The test is limited to the detection of antibodies to Malaria both *Plasmodium falciparum* (pf) and *Plasmodium vivax* (pv) simultaneously. Although the test is very accurate in detecting