

One Step Malaria P.f/P.v Whole Blood Test

Catalog No. W56-C

INTENDED USE

Wondfo One Step Malaria P.f/P.v Whole Blood Test Cassette is a rapid self-performing, qualitative, two site sandwich immunoassay, utilizing whole blood for the detection of *P.falciparum* specific histidine rich protein-2 (P.f HRP-2) and *P.vivax* specific pLDH. The test may also be used for specific detection and differentiation of *P. falciparum* and *P. vivax* malaria in whole blood samples and for the follow up of anti-malarial therapy.

For in vitro diagnostic use only. For healthcare professional use only.

SUMMARY

Malaria remains one of the most serious tropical and subtropical diseases in many countries of the world. It is rampant in most areas of the tropics. Malaria is caused by a parasite that is transmitted from one person to person 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*. Malaria also has been reported from blood transfusions or congenitally from mother to child. It is estimated to affect more than 500 million people causing between one and three million deaths every year.

PRINCIPLE

Wondfo One Step Malaria P.f/P.v Whole Blood test utilizes the principle of immunochromatography. As the test sample flows through the membrane assembly of the device after addition of the buffer, the coloured monoclonal P.f specific HRP-2, P.v specific pLDH colloidal gold conjugate antibodies complexes the proteins in the lysed sample. This complex moves further on the membrane to the test region where it is immobilized by the P.f specific HRP-2 antibody / P.v specific pLDH coated on the membrane. This leads to formation of a coloured band in the respective regions which confirms a positive test result. Absence of a coloured band in the appropriate test region indicates a negative test result for the corresponding antigen.

The unreacted conjugate along with the rabbit globulin colloidal gold conjugate and unbound complex if any, move further on the membrane and are subsequently immobilized by anti-rabbit antibodies coated on the membrane at the control region, forming a pink / purple band. This control band serves to validate the test performance.

PRECAUTIONS AND WARNINGS

1. This kit is for in vitro use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond the expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
6. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards. Avoid splashing or aerosol formation. Clean up spills thoroughly using an appropriate disinfectant.
7. Keep out of the reach of children.
8. **DISPOSAL OF THE DIAGNOSTIC:** The used-device has the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.

CONTENT OF THE KIT

1. Individual pouches, each containing:
 - Test device
 - Desiccant pouch
 - 5µl sample dropper
2. Alcohol pads (optional)
3. Lancets (optional)
4. Clearing buffer in a dropper bottle.
5. Leaflet with instructions for use.

STORAGE AND STABILITY

1. Stored at 4°C to 30°C in the sealed foil pouch up to the expiration date.
2. Keep away from sunlight, moisture and heat.
3. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

Collection by venipuncture

1. Collect the whole blood into the collection tube (using the suitable anti-coagulant) by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2°C ~ 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use.

Collection using a lancet

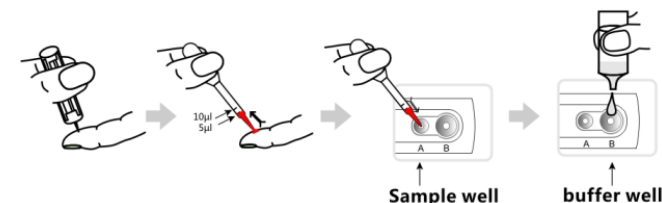
1. Clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with a sterile lancet. Wipe away the first drop of blood with sterile cotton.

3. Take a dropper provided, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the dropper.

TEST PROCEDURE

Allow the device, buffer and specimen to equilibrate to room temperature (10°C ~30°C) prior to testing.

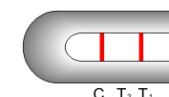
1. Remove the test cassette from the foil pouch by tearing at the notch and place it on a level surface.
2. Slowly add 5 µl of whole blood to the sample well (A) and then add 4 drops (90~100ul) of clearing buffer to the buffer well (B).
3. As the test begins to work, you will see purple color move across the result window in the center of the test device.
4. Wait for 15 minutes and read results. Do not read results after 30 minutes.



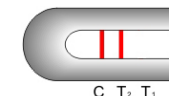
INTERPRETATION OF RESULTS

Positive (+)

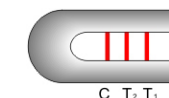
1. The presence of two color bands ("T1" and "C") indicates a positive result for a infection with *P. falciparum*



2. The presence of two color bands ("T2" and "C") indicates a positive result for a infection with *P. vivax*.



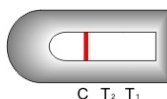
3. The presence of three color bands ("T1", "T2" and "C") indicates a positive result for "mixed" infection.



Negative (-)

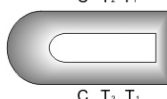
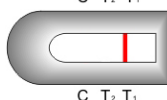
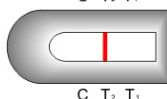
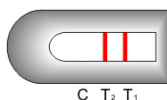
The presence of only one band ("C") within the result window

indicates a negative result.



Invalid

If the color band ("C") 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.



QUALITY CONTROL

Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

The test is limited to the detection of *P.falciparum* specific histidine rich protein-2 (P.f HRP-2) and *P.vivax* specific pLDH. Although the test is accurate in detecting antigens of Malaria P.f/P.v, a low incidence of false results can occur. Other clinically available test 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

1. Wondfo One Step Malaria P.f/P.v Whole Blood Test have a sensitivity of >90% at densities above 40-100 parasites /ul blood

A. Sensitivity and Specificity

Collect 369 patients' samples from several medical institutions. Test these samples using microscopic examination method and colloidal gold method. Compare sensitivity and specificity between. These samples were obtained from patients attending infection clinics.

Table 1 Result of the sensitivity and specificity between (Malaria P.f):

	P.f Positive sample (n=123)	P.f Negative sample (n=202)	Sensitivity	Specificity
Wondfo	135/139	224/230	97.1%	97.4%
Microscopic examination	139/139	230/230	-	-

Table 2 Result of the sensitivity and specificity between (Malaria P.v):

	P.v Positive sample (n=158)	P.v Negative sample (n=167)	Sensitivity	Specificity
Wondfo	167/173	191/196	96.5%	97.4%
Microscopic examination	173/173	196/196	-	-

B. Precision

1. Within run precision was determined by using 10 replicates of four different specimens containing different concentrations of antigen. 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 antigen in 3 different lots of test devices. Again negative and positive results were correctly identified 100% of the time.

BIBLIOGRAPHY OF SUGGESTED READIN

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. 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.
3. Alon Warburg and Imogene Schneider. In Vitro Culture of the Mosquito Stages of Plasmodium falciparum. Experimental parasitology 76, 121-126 (1993).

INDEX OF SYMBOLS



Keep away from sunlight



Store between 4°C and 30°C



Keep dry



Do not re-use