One Step Malaria P.f Whole blood Test

Catalog No. W37-C

INTENDED USE

Wondfo One Step Malaria P.f Whole Blood Test cassette is designed as a rapid self-performing, qualitative, two site sandwich immunoassay for the detection of P. falciparum specific histidine rich protein – 2 (P.f HRP-2) in whole blood samples. It is a sensitive and specific test for the detection of P.falciparum malaria. The assay is intended for use with whole blood and does not require additional instruments.

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

SUMMARY

Malaria remains one of the most serious tropical diseases in many parts 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: *P. falciparum, P.vivax, P. malariae,* and *P.ovale.* It is transmitted by the bite of the infected Anopheles mosquito. 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. Though, to a large extent, it has been eradicated from large parts of North America and Europe,

PRINCIPLE

Wondfo One Step Malaria P.f 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 colored monoclonal P.f specific HRP-2 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 which will lead to a formation of color band. While the color band will appear at the test region in falciparum positive samples. Absence of this color band in the test region indicates a negative test result.

To serve as a procedure control, a colored line will appear at the control region (C), if the test has been performed properly.

PRECAUTIONS

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. 25 Individual pouches, each containing:
   - Test Device
   - Desiccant pouch
   - 5µl sa mple dropper
2. Alcohol pads (optional)
3. Sterile lancets (optional)
4. 5 ml clearing buffer in a dropper bottle.
5. Leaflet with instructions for use.

Optional: not included in the standard kit package, please contact your local distributor for ordering.

STORAGE AND STABILITY

1. Stored at room temperature (4ºC to 30ºC) 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

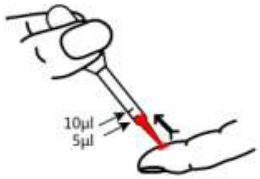
1. Collect the whole blood into the collection tube （using the suitable anti-coagulant）by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2°C ~ 8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature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

Collection using a lancet

1. Select the finger for puncture, usually the side of the third or fourth finger. Clean the area to be lanced with an alcohol pad. Allow the finger to dry thoroughly.

2. Using a sterile lancet, puncture the skin just off the centre of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away the first drop of blood with a sterile swab. Allow a new drop of blood to form. If blood flow is inadequate, the subject's finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume. Avoid 'milking' the finger.

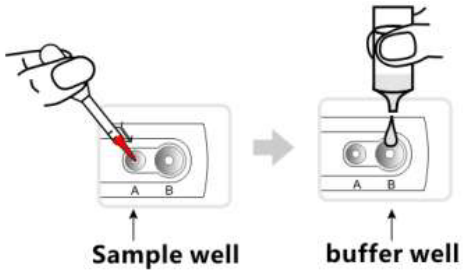
3. Take a dropper provided, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the dropper.



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 (+)
Color bands are visible in both the control region and the test region. It indicates a positive result for an infection with *P. falciparum*.

Negative (-)
A color band is visible in the control region. No color band appears in the test region. It indicates that the concentration of the P.f specific HRP-2 is zero or below the detection limit of the test.

Invalid
No visible band at all, or there is a visible band only in the test region but not in the control region. Repeat with a new test kit. If test still fails, please contact Wondfo or the distributor for technical assistance.
Note: There is no meaning attributed to line color intensity or width.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE

The test is limited to the detection of P.falciparum specific histidine rich protein-2 (P.f HRP-2). Although the test is accurate in detecting antigens of Malaria P.f, 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

A. Sensitivity and Specificity
The 547 blood samples were tested by Wondfo One Step Malaria P.f Whole blood Test (Colloidal Gold Method) and microscopic examination of blood smears (Gold standard for malaria detection). Compared the two methods and calculated the sensitivity and specificity of Wondfo devices, and the coincidence between. The test result is as below:

Microscopic examination	Wondfo One Step Malaria P.f Whole blood Test		
	Positive	Negative	Total
Positive	323	17	340
Negative	0	207	207
Total	323	224	547

Result gave sensitivity of 95%(323/340), a specificity of 100% (207/207) for Wondfo Malaria P.f Whole Blood Test.

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 READING

1. **Kakkilaya BS.** Rapid Diagnosis of Malaria. Lab Medicine. 2003 Aug; 8(34):602-608
2. **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).
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. **Alon Warburg and Imogene Schneider.** In Vitro Culture of the Mosquito Stages of Plasmodium falciparum. Experimental parasitology 76, 121-126 (1993).

INDEX OF SYMBOLS

	See instruction for use		Tests per kit		Manufacturing date
IVD	For *in vitro* diagnostic use only		Expiry date		Do not reuse
	Store between 4 ~ 30 ℃	LOT	Batch number	REF	Catalog #
	Keep away from sunlight		Keep dry	EC REP	Authorized Representative
CE					