KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
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GERMAS

Berdasarkan :

Peraturan Menteri Kesehatan R.I No.1190/Menkes/Per/VIII/2010 tanggal 23 Agustus 2010 tentang Izin Edar Alat Kesehatan dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

A L A T K E S E H A T A N

KEMENKES RI AKL 20303714220

Nama	:	**WONDFO Malaria HRP2 / PLDH (P.f/Pan)**
Jenis Produk	:	Plasmodium species antigen detection assays
Kategori Produk	:	Peralatan Imunologi dan Mikrobiologi
Sub Kategori	:	Pereaksi Serologi
Type / Ukuran	:	Cassette
Kemasan	:	Dus, kit, isi 25 test
Nama Pabrik	:	GUANGZHOU WONDFO BIOTECH CO.,LTD., China
Nama Pendaftar	:	PT. EXXEL UTAMA, DKI Jakarta
Atas dasar lisensi dari	:	-
Ketentuan	:	1. Persetujuan izin edar berlaku sampai dengan 13 Februari 2022. 2. Wajib menyampaikan laporan berkala setiap 1 (satu) tahun terhadap jenis dan akibat efek samping dari produk yang diedarkan.
Persyaratan	:	1. Apabila dikemudian hari ada pihak lain yang lebih berhak atas nama keagenan diatas, sesuai dengan ketentuan yang berlaku, pendaftar bersedia melepaskan nama keagenan produk tersebut. 2. Apabila dikemudian hari terdapat kekeliruan, maka persetujuan ini akan ditinjau kembali.

03 Agustus 2017
a.n. Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT

drg. Arianti Anaya, MKM
NIP. 19640924 199403 2 001

Wondfo®

One Step Malaria HRP2/pLDH (P.f/Pan) Test

Catalog No. W62-C

INTENDED USE

Wondfo One Step Malaria HRP2/pLDH (P.f/Pan) Test is intended for use by healthcare professionals and as qualitative screening *in vitro* diagnostic test for detection of P.falciparum specific histidine rich protein-2 (P.f HRP-2) and Pan specific pLDH. The test may also be used for differentiation of P.falciparum and other malarial species in whole blood samples and for the anti-malarial treatment monitoring. This test is not automated and does not require any additional instrument.

For *in vitro* diagnostic 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 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. It also has been reported that Malaria can transmit by 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 HRP2/pLDH (P.f/Pan) Test uses the principle of immunochoromatograhpy. After adding the buffer, the sample flows through the membrane of the test device, and the antigens bind to the monoclonal P.f specific HRP-2, Pan specific pLDH colloidal gold conjugate antibodies. These complexs move further to the test region on the membrane, where is immobilized by the P.f HRP-2 antibody/Pan pLDH antibody, and that will produce a purple color band(s), which indicates a positive result. Absence of the color band(s) in the Test Region (T) indicates a negative test result.

To serve as a procedure control, a colored line will appear at the Control Region (C).

PRECAUTIONS

1. This kit is for in vitro use only. Do not swallow.
2. All specimens should be treated as biohazard.
3. Icteric, lipaemic, hemolytic, heat-treated and contaminated blood may cause erroneous results.
4. Discard the test after use. Each test cannot be used more than once.
5. Do not use test kit beyond the expiration date.
6. Do not use the kit if the pouch is punctured or not well sealed.
7. Keep out of the reach of children.
8. All specimens and used-devices have infectious risks. The disposal process must follow the local infectious disposal law or laboratory rule.

MATERIALS

MATERIALS PROVIDED

1. Individual pouches, each containing:
   - Test cassette
   - 5 µL sample dropper
   - Desiccant pouch

(The desiccant is for storage purposes only, and is not used in the test procedures.)

2. Alcohol pads (optional)
3. Sterile lancets (optional)
4. Clear buffer (5 mL/bottle): 3%TritonX100
5. Leaflet with instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Sterile lancets (for fingerstick whole blood only)
3. Alcohol pads
4. Capillary tube (for fingerstick whole blood only)
5. Timer

STORAGE AND STABILITY

1. The test devices should be stored at 4ºC~30ºC.
2. The unopened test devices are stable until the expiration date printed on the package.
3. Keep away from sunlight, moisture and heat.
4. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

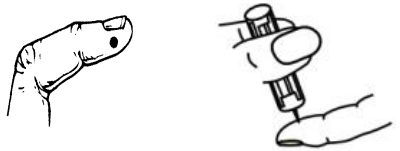
Collection by venipuncture

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, more than three days. Freezing is recommended. They should be brought to room temperature prior to use.

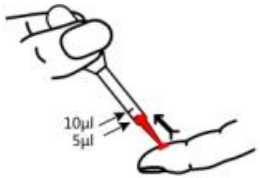
Collection using a lancet

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.



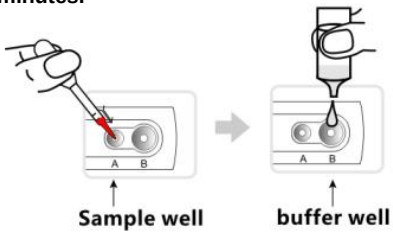
3. Take a dropper provided, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the dropper.



TEST PROCEDURE

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

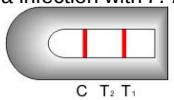
1. Remove the test cassette from the foil pouch by tearing at the notch and place it on a level surface.
2. Slowly add 5 µL of whole blood into the sample well (A) and then add 4 drops (90 µL~100 µL) of clearing buffer into the buffer well (B).
3. As the test begins to work, you will see purple color 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.**



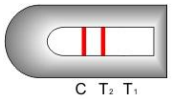
INTERPRETATION OF RESULTS

Positive (+)

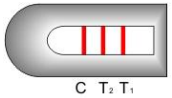
1. The presence of two color band ('T1' and 'C') indicates a positive result for a infection with *P. falciparum.*



2. The presence of two color bands ('T2' and 'C') indicates a positive result for Non-*P. falciparum (P. vivax, P. malariae* or *P.ovale)* infection.

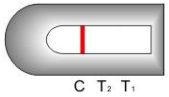


3. The presence of three color bands ('T1', 'T2'and 'C') indicates a positive result for *P. falciparum* monoinfection or "mixed" infection.



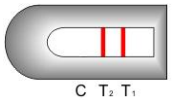
Negative (-)

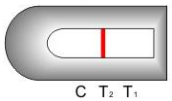
The presence of only one band (C) within the result window indicates a negative result.

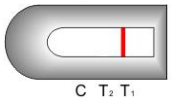


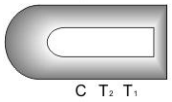
Invalid

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 to retest the specimen.









QUALITY CONTROL

Though there is an internal procedural control line in the control region of test device, 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 controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. This test has been developed for testing whole blood samples only. The performance of this test using other specimens has not been substantiated.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of P.falciparum specific histidine rich protein-2 (P.f HRP-2) and Pan specific pLDH.
4. Do not mix reagent of different lots.

PERFORMANCE CHARACTERISTICS

1. Wondfo One Step Malaria HRP2/pLDH (P.f/Pan) Test have a sensitivity of >90% at densities above 50~100 parasites/μL blood.

A. Sensitivity and Specificity

Collect 325 patients' samples from several medical institutions. Test these samples using microscopic examination method and colloidal gold method. 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 One Step Malaria HRP2/pLDH (P.f/Pan) Test	118/123	196/202	96.0%	97.0%
Microscopic examination	123/123	202/202	-	-

(1) Sensitivity of One Step Malaria HRP2 (P.f) Test = 118/123×100%=96.0%
(2) Specificity of One Step Malaria HRP2 (P.f) Test = 196/202×100%=97.0%

Table 2 Result of the sensitivity and specificity between (Malaria Pan):

	Pan Positive sample (n=158)	Pan Negative sample (n=167)	Sensitivity	Specificity
Wondfo Rapid Test	153/158	161/167	96.8%	96.4%
Microscopic examination	158/158	167/167	-	-

(1) Sensitivity of One Step Malaria pLDH (P.pan) Test = 153/158×100%=96.8%
(2) Specificity of One Step Malaria pLDH (P.pan) Test = 161/167×100%=96.4%

B. Precision

1. Within-run precision was determined by using four specimens with different concentrations of antigen to do the test, and each specimen was tested repeatedly for 10 times.

2. Between-run precision was determined by using four specimens with different concentrations of antigen to do the test, and each specimen was tested with 3 different lots of test cassette.

BIBLIOGRAPHY

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

IVD In Vitro Diagnostic Use	See Instruction for Use	Expiry Date
Tests per Kit	Manufacturing Date	Keep Dry
LOT Batch Number	EC REP Authorized Representative	Keep away from Sunlight
Manufacturer	Do not reuse	REF Catalog #
Store between 4～30℃		

Guangzhou Wondfo Biotech Co., Ltd.
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