THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR WONDFO (MALARIA P.F (HRP2/PLDH) TEST)

Version number 2.0, 18.05.2026

TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma – Tanzania, Telephone: +255 (26) 2961989/2061990/+255 (22) 2450512/2450751/2452108, Email: info@tmda.og.tz, Website: **www.tmda.go.tz**

Toll free: 0800110084

1. Introduction

Wondfo is a class C in-vitro diagnostic device belonging to the Infectious disease - parasitology specialty category. It is approved in Tanzania as kit for use in adults, children, elderly etc. by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 25 MDR 0205
Brand Name (if relevant)	Wondfo
Common name	Malaria P.F (HRP2/PLDH) Test
Class of the device and rule applied	Class C as per Rule 3 for classification of In Vitro Diagnostic Devices
GMDN code and term	52336, Plasmodium falciparum antigen IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	Guangzhou Wondfo Biotech Co. Ltd. 510663 no. 8 Lizhihishan Road, Luagang district Guangzhou China
Name and address(es) of local responsible person (LRP).	Qualtrust Company Limited, Trust House, 4th Floor, Plot No. 58, Block 29B, Mwananyamala, Komakoma, Mwinyijuma Road, Dar es Salaam

1.2. Assessment Procedure

The application for registration of Wondfo was submitted on 03.01.2025. The product underwent abridged assessment. Assessment was completed in 2 rounds of evaluation. Wondfo was registered on 18.12.2025

2. Technical information

2.1. Intended use

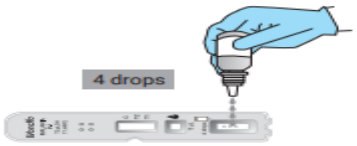
The intended use of Wondfo as declared by the manufacturer and approved by TMDA is an immunochromatographic, rapid diagnostic assay intended for the qualitative detection of P. falciparum specific histidine rich protein-2 (P.f HRP2) and P. falciparum specific pLDH (P.f pLDH) in human fingerstick whole blood and venous whole blood. Wondfo is approved for use in healthcare settings, point of care by trained professionals only.

2.2. Device details and features

Wondfo is a single device with no additional components or accessories. Wondfo has been registered as a kit which consists of Cassette, Instruction for use, Alcohol prep pad, the invented cup Sterile lancet, and Blood lancet for single use

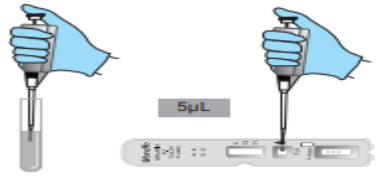
Wondfo is a manually operated device. It is used for diagnosis of malaria. Wondfo operates by immunochromatographic, rapid diagnostic assay. The test out-put is qualitative.

The type of specimen used is whole blood and is collected by human fingerstick and venous collection

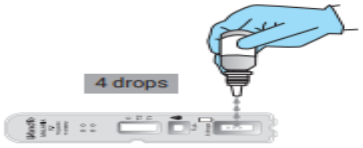


2. Test procedure for venous whole blood

A. Please gently mix the venous blood specimen by inverting the blood collection tube to make it homogenous. Take 5μL venous whole blood specimen with a pipette and drop it into the center of the sample well vertically.



B. Add 4 drops (about 100μL) of buffer into the buffer well vertically, and start timing.



3. Interpretation

A. Read the results after 15 minutes but no more than 30 minutes.

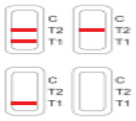
B. To avoid confusion, discard the test device after reading the result.

15-30 mins

QUALITY CONTROL

1. Internal control: This kit contains a built-in control feature as a procedural control, the control region (C). A colored line develops in the control region (C) after addition of the specimen and buffer. If a colored line does not-develop in the C region, the test is invalid. Review the procedure and repeat the test with a new device.
2. External control: The test kit does not provide external control.

INTERPRETATION OF RESULTS

Lines that you see	Picture	Read and Interpretation of Results
No line at 'C' (control)		**Result: Invalid.** Action: Take a new cassette and repeat the test.Please contact the local distributor or manufacturer if invalid results continuously appear.
Line at 'C' and No other line		**Result: Negative.** Action: No

Lines that you see	Picture	Read and Interpretation of Results
Line at 'C' and at 'T1' and/or 'T2'	1  2  3 	**Result: Positive.** 1. Line at 'C' , 'T1' and 'T2' indicates positive for P.f HRP2 and P.f pLDH. 2. Line at 'C' and 'T1' indicates positive for P.f HRP2. 3. Line at 'C' and 'T2' indicates positive for P.f pLDH. Note: Line intensity may vary from faint to strong intensity. Consider a faint test line as a positive result. Action: No

2.3. Commercial presentation

There are three (3) approved commercial presentations as follows: One test cassette and desiccant in the foil pouch. 25, 40 and 100 pouches are placed in a box

Additional contents include quick guide, sterile lancet or blood lancet, test cassette desiccant, inverted cup and alcohol prep pad

2.4. Items required but not submitted

- Timer
- Protective gloves
- Specimen and test waste container
- Sterile cotton swab/ball

3. Storage instructions

3.1.1. Shelf-life

24 months.

3.1.2. Storage conditions

The recommended storage conditions are Store the kit at 1˚C-40˚C.

3.1.3. Shipping conditions

The recommended shipping conditions is 1-40°C

4. Manufacturing site audit

The manufacturer of the device is Guangzhou Wondfo Biotech Co., Ltd. No.8, Lizhi Shan Road, Science City, Huangpu District, 510663, Guangzhou, P.R. China. sales@wondfo.com.cn

Quality audit of the manufacturing facility was conducted through site visit, on 12th – 13th June, 2019.The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: precision (repeatability and reproducibility), analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at Centers for Disease Control and Prevention on behalf of WHO in the fourth quarter of 2022, according to protocol PQDx_317, version 3.1. The following parameters were tested; precision (repeatability and reproducibility), clinical sensitivity and clinical specificity.

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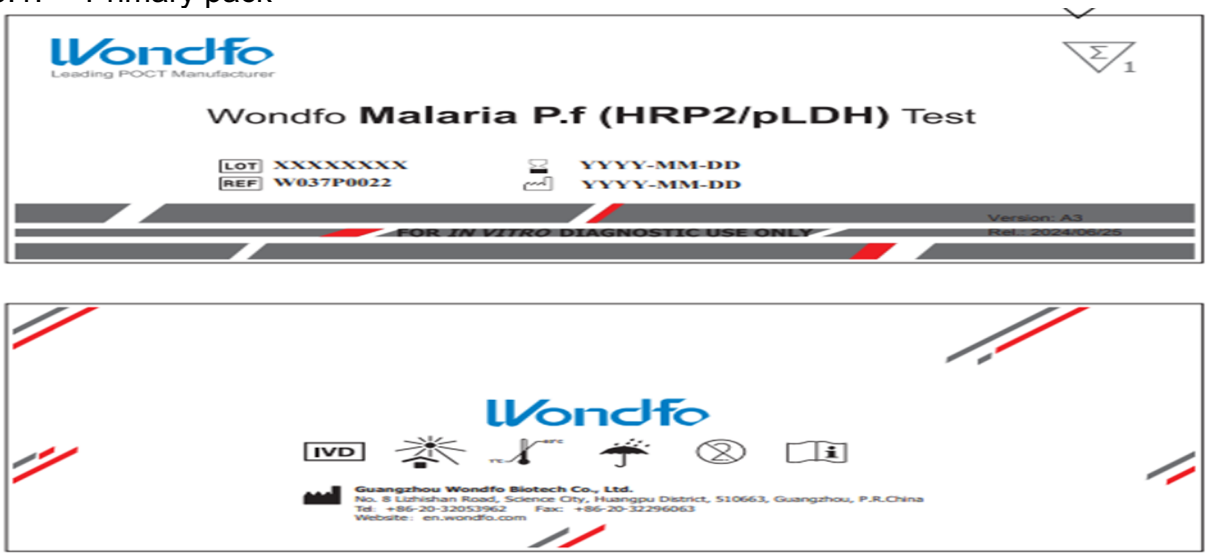
Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 100% respectively. The studies further concluded that Wondfo is capable of consistently producing accurate and reliable test output.

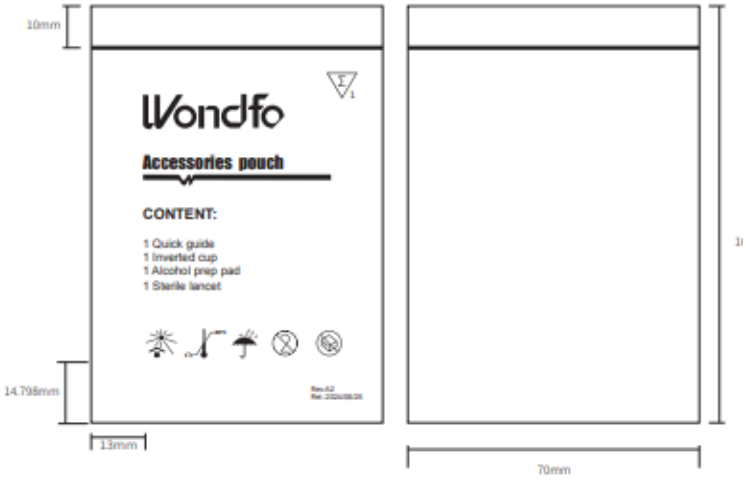
6. Product label and instructions for use

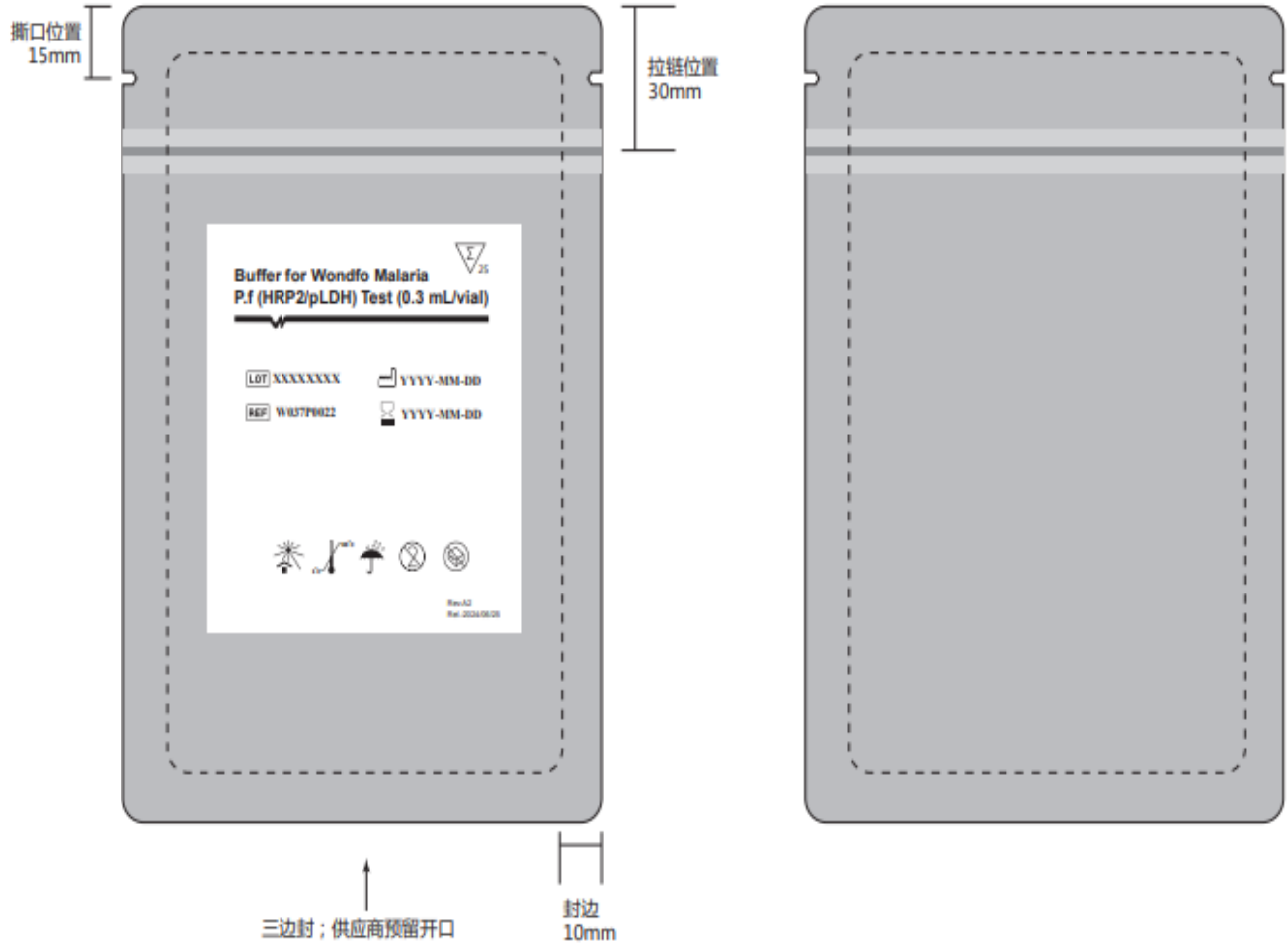
The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The package insert includes all the relevant information to ensure correct and safe use of the device by intended user.

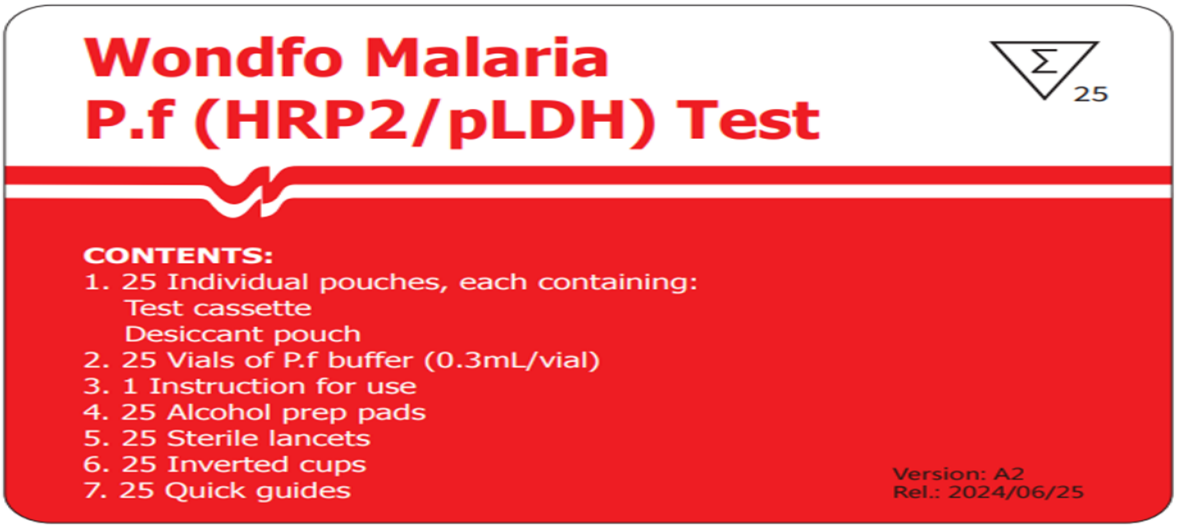
6.1. Primary pack

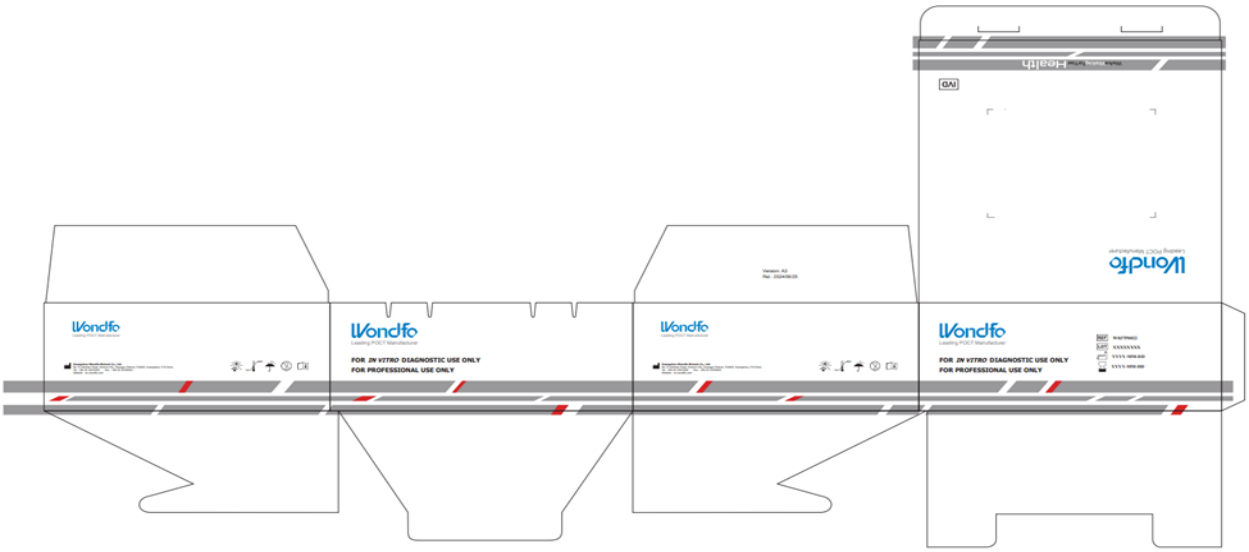



10mm
Wondfo
Accessories pouch
CONTENT:
1 Quick guide
1 Inverted cup
1 Alcohol prep pad
1 Sterile lancet
14.798mm
13mm
70mm


撕口位置
15mm
拉链位置
30mm
Buffer for Wondfo Malaria
P.f (HRP2/pLDH) Test (0.3 mL/vial)
LOT XXXXXXXX
YYYY-MM-DD
REF W037P0022
YYYY-MM-DD
三边封；供应商预留开口
封边
10mm

6.2. Secondary pack





6.3 Instructions for use/Package insert
View the product insert at the last page

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. Wondfo is recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA	NA	NA	NA	NA

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	**Date**	**Description of update**	**Section(s) Modified**	**Approval date**

Wondfo Malaria P.f (HRP2/pLDH) Test

CATALOG No.

W037P0022 W037P0028 W037P0030
W037P0024 W037P0033 W037P0035
W037P0037

INTENDED USE

The Wondfo Malaria P.f (HRP2/pLDH) Test is an immunochromatographic, rapid diagnostic assay intended for the qualitative detection of *P. falciparum* specific histidine rich protein-2 (P.f HRP2) and *P. falciparum* specific pLDH (P.f pLDH) in human fingerstick whole blood and venous whole blood. It is intended to be used by laboratory professionals and at point-of-care by healthcare workers or trained lay providers. It is used as an aid for diagnosis of *P. falciparum* Malaria infection for symptomatic patients including paediatric testing. Results from the Wondfo Malaria P.f (HRP2/pLDH) Test should not be used as the sole basis for diagnosis.

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

BACKGROUND INFORMATION

Malaria remains one of the most serious tropical diseases in many regions of the world, mainly occurring in tropical and subtropical areas. Malaria is caused by a parasite that commonly infects the *Anopheles* mosquito which feeds on human blood. There are four kinds of malaria parasites that can infect humans: *P. falciparum*, *P. vivax*, *P. malariae*, and *P. ovale*. Malaria can also be transmitted through blood transfusions, organ transplantation or shared needles/syringes contaminated with blood from an infected person. It can also be transmitted congenitally from mother to her unborn infant. It is estimated to affect more than 200 million people worldwide and cause more than 400,000 deaths every year[1][4][8].

PRINCIPLES OF THE PROCEDURE

The Wondfo Malaria P.f (HRP2/pLDH) Test utilizes the principles of immunochromatography to detect two targets: *P. falciparum* specific histidine rich protein-2 (P.f HRP2) and *P. falciparum* specific pLDH (P.f pLDH) in human fingerstick whole blood and venous whole blood.

After adding specimen into the sample well and adding buffer into the buffer well, the specimen-buffer mixture migrates towards the other end of the cassette by capillary action. The antigen in the specimen will bind the antibody-gold colloid to form the antigen-antibody-gold colloid complex. The complex migrates further to capture P.f HRP2 specific antibody / P.f pLDH specific antibody that is pre-coated on the test line of the cassette. When a target antigen (P.f HRP2 and/or P.f pLDH) level is at or above the limit of detection (LoD) of the assay, the test line will form a visible red line, indicating a positive result.

Rabbit IgG-gold colloid combines with goat anti-rabbit IgG polyclonal antibody in C line (control line) to form a red reaction line. The control line is used for procedural control and shows only that the buffer has been applied successfully and that the active ingredients of the main components on the strip are functional.

WARNINGS AND PRECAUTIONS

1. This kit is for *in vitro* use only.
2. Apply standard biosafety precautions for handling and disposal of potentially infective material.
   - Handle all specimens as potentially infectious.
   - Wear gloves while handling specimens and performing the test.
   - Avoid splashing and aerosol formation.
   - Clean up spills thoroughly using an appropriate disinfectant.
3. **Do not** reuse the test cassette, inverted cup, lancet, and alcohol prep pad.
4. **Do not** use the kit beyond the expiration date.
5. **Do not** use the test cassette if the pouch is punctured or improperly sealed.
6. **Do not** mix a buffer and a test cassette from different lots.
7. **Do not** open the sealed pouch until you are ready to conduct the assay. Once opened, use the test cassette within 1 hour.
8. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials as biohazardous waste.
9. Read the instructions for use completely before using the kit. Failure to follow directions may yield inaccurate test results.
10. DISPOSAL OF DIAGNOSTIC DEVICE: The used device has risk of infection. The process for disposing the diagnostic device must follow local infectious waste disposal laws or laboratory regulations.
11. Keep out of reach of children.
12. The Buffer contains 2% Triton X-100, which presents no hazard to the user if normal laboratory safety precautions are followed. Wear protective gloves. In case of contact with skin and/or the eyes, rinse with water immediately. If irritation or signs of toxicity occur, seek medical attention. Follow local regulation or laws to dispose the Buffer.

KIT CONTENTS

There are 7 configurations of the test kits. The inclusion of quick guide, sterile lancet or blood lancet for single use are optional/available in different combinations per end user's request.

A. Kit components

Each individually sealed pouch contains one test cassette and one desiccant pouch (for storage purposes only).

The kit component configurations are provided below:

Catalogue No. / Components	W037P0022	W037P0024	W037P0028	W037P0030	W037P0033	W037P0035	W037P0037
Cassette (pcs)	25	40	25	25	40	40	100
Instruction (pcs)	1	1	1	1	1	1	1
Buffer	25×0.3mL/vial	40×0.3mL/vial	2×5mL/bottle	2×5mL/bottle	4×5mL/bottle	4×5mL/bottle	8×5mL/bottle
Quick guide (pcs)	25 pouches, each containing one quick guide, one inverted cup, one alcohol prep pad, one sterile lancet.	40 pouches, each containing one quick guide, one inverted cup, one alcohol prep pad, one sterile lancet.	/	/	/	/	/
Inverted cup (pcs)			25	25	40	40	100
Alcohol prep pad (pcs)			25	25	40	40	100
Sterile lancet (pcs)			25	/	40	/	100
Blood lancet for single use(pcs)	/	/	/	25	/	40	/

B. Reactive ingredients of main components

The test strip is coated with gold conjugates (Malaria P.f HRP2 monoclonal antibody-gold colloid, Malaria P.f pLDH monoclonal antibody-gold colloid, rabbit IgG-gold colloid), test line (Malaria P.f HRP2 monoclonal antibody and Malaria P.f pLDH monoclonal antibody) and control line (goat anti-rabbit IgG polyclonal antibody).

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer
2. Protective gloves
3. Specimen and test waste container
4. Sterile cotton swab/ball

Note: If whole blood is collected by venipuncture, venipuncture blood collection materials are required in addition to a precision pipette and pipette tips.

STORAGE AND STABILITY

1. Store the kit at 1°C-40°C. The shelf life of the kit is 24 months.
2. Use the test cassette within 1 hour after opening. For 0.3 mL buffer, discard after every use. For 5 mL buffer, store at 1°C-40°C for no more than 8 weeks after opening.
3. Use the kit at 20%-90% humidity and 15°C-40°C, on a clean and flat surface.
4. Recap and store the buffer (5mL) in the original container after use.
5. Keep away from sunlight, moisture, and heat.
6. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

Fingerstick whole blood:

1. Wash hands and put on protective gloves. Select the middle or ring finger of the patient and avoid calloused areas of the finger. Clean the finger to be lanced with an alcohol prep pad.
2. Prick the lateral side of fingertip with a lancet. Gently squeeze the end of fingertip and wipe off the first drop of blood with a sterile cotton swab/ball. Squeeze the fingertip again and allow a new drop of blood to form.
3. Draw 5 microliter (5μL) of blood with an inverted cup. Test immediately after whole blood specimens collected by fingerstick.

Venous whole blood:

1. Draw venous whole blood via standard phlebotomy procedures into a blood collection tube with anticoagulant (EDTA, sodium citrate, or heparin sodium).
2. If immediate testing is not possible then the specimen may be stored at 2°C-8°C for up to 72 hours before testing.
3. The specimens should be stored at -70°C or below for longer storage.

Note:

1.Prior to testing, bring specimens to room temperature slowly and mix well gently once thawed. Do not freeze and thaw the specimens repeatedly.In case repeated freezing and thawing of specimens is required, no more than 5 cycles should be allowed.

2. To ensure the accuracy of test result, whole blood specimens partly or completely coagulated should be excluded even though they are not validated.

TEST PROCEDURE

Bring all specimens and kit components to room temperature (15°C- 40°C) before testing. When ready to test, remove the test cassette from the foil pouch by tearing the notch and place it on a flat, dry surface. Label the device with specimen ID number.

For 0.3mL buffer configurations, please refer to QUICK GUIDE. For 5mL buffer configurations, please follow the instruction as below.

1. Test procedure for fingerstick whole blood

A. Wash hands and put on protective gloves before testing. Wipe the fingertip to be lanced with an alcohol prep pad.Select the middle or ring finger for sampling and avoid calloused areas of the finger.

B. Prick the lateral side of fingertip with a lancet. Wipe off the first drop of blood with a sterile cotton swab/ball.Squeeze the fingertip again and allow a new drop of blood to form.

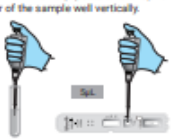
C. Dip the circular end of the inverted cup into the blood specimen (5μL).

D. Place the circular end of the inverted cup into the sample well.

E. Add 4 drops (about 100μL) of buffer into the buffer well vertically and start timing.

2. Test procedure for venous whole blood

A. Please gently mix the venous blood specimen by inverting the blood collection tube to make it homogenous. Take 5μL venous whole blood specimen with a pipette and drop it into the center of the sample well vertically.



B. Add 4 drops (about 100μL) of buffer into the buffer well vertically, and start timing.

3. Interpretation

A. Read the results after 15 minutes but no more than 30 minutes.

B. To avoid confusion, discard the test device after reading the result.

15-30 mins

QUALITY CONTROL

1. Internal control: This kit contains a built-in control feature as a procedural control, the control region (C). A colored line develops in the control region (C) after addition of the specimen and buffer. If a colored line does not develop in the C region, the test is invalid. Review the procedure and repeat the test with a new device.
2. External control: The test kit does not provide external control.

INTERPRETATION OF RESULTS

Lines that you see	Picture	Read and Interpretation of Results
No line at 'C' (control)		**Result: Invalid.** Action: Take a new cassette and repeat the test.Please contact the local distributor or manufacturer if invalid results continuously appear.
Line at 'C' and No other line		**Result: Negative.** Action: No
Lines that you see	Picture	Read and Interpretation of Results
1 Line at 'C' , 'T1' and 'T2' indicates positive for P.f HRP2 and P.f pLDH. 2 Line at 'C' and 'T1' indicates positive for P.f HRP2. 3 Line at 'C' and 'T2' indicates positive for P.f pLDH.		**Result: Positive.** 1. Line at 'C' , 'T1' and 'T2' indicates positive for P.f HRP2 and P.f pLDH. 2. Line at 'C' and 'T1' indicates positive for P.f HRP2. 3. Line at 'C' and 'T2' indicates positive for P.f pLDH. Note: Line intensity may vary from faint to strong intensity. Consider a faint test line as a positive result. Action: No

Note: Please contact the local distributor or manufacturer if there is suspicion of an increased rate of false negative or positive results.

LIMITATIONS OF PROCEDURE

1. The kit is a qualitative assay designed to detect P. falciparum specific histidine rich protein-2 (P.f HRP2) and P. falciparum specific pLDH (P.f pLDH) antigens in human whole blood only.
2. Strictly operate according to the instructions for use when testing. False operation will result in a false result.
3. Use EDTA, heparin sodium, and sodium citrate as anticoagulants. Do not use other anticoagulants.
4. False-negative results can occur in the following conditions:
   - Very low antigen concentrations/parasite densities, for instance < 100 parasites/ μl. Note that most clinical cases have higher parasite densities.
   - Very high parasite densities (very exceptional, prozone or high-hook effect) for the HRP2 antigen.
   - Deletions in the HRP2 gene result in no production of the HRP2 antigen, which is of particular relevance for mRDTs that detect this antigen. These deletions were first identified in the Peruvian Amazon but have since been reported in various malaria-endemic regions worldwide.
   - High fraction of interstitial fluid due to "milking" of fingertip.
5. The presence of the control line only means that migration of added liquid occurred. It does not guarantee that:
   - The correct specimen has been used.
   - The specimen has been applied correctly.
   - The specimen and kit have been correctly stored.
   - The test procedure has been followed correctly.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but instead should be determined by a health-care provider in conjunction with clinical findings and the results from other laboratory tests and evaluations. Results from the Wondfo Malaria P.f (HRP2/pLDH) Test should not be used as the sole basis for diagnosis.
7. The product can give a false positive Pf result even after the patient was treated for malaria several weeks before testing. The test cannot be used to monitor treatment response to antimalarials.

PERFORMANCE CHARACTERISTICS[5][6]

Clinical performance study

1. Internal Evaluation

Place of Evaluation	SD Bioline	Wondfo Malaria P.f (HRP2/pLDH) Test			
		Positive	Negative	Total	Test Result (95% CI)
Wondfo laboratory	P.f Positive	102	0	102	Sensitivity:100.00% (96.37-100.00%)
	P.f Negative	1	625	626	Specificity:99.84% (99.10-99.97%)

*Specimen type used for SD Bioline and Wondfo: venous whole blood.

2. External Evaluation

2.1 Diagnostic Sensitivity and Specificity

Place of Evaluation	SD Bioline	Wondfo Malaria P.f (HRP2/pLDH) Test			
		Positive	Negative	Total	Test Result (95% CI)
Cote d'Ivoire	P.f Positive	183	0	183	Sensitivity:100.00% (97.94-100.00%)
	P.f Negative	3	356	359	Specificity:99.16% (97.56-99.71%)
Rwanda	P.f Positive	176	0	176	Sensitivity:100.00% (97.85-100.00%)
	P.f Negative	0	364	364	Specificity:100.00% (98.96-100.00%)
Cameroon	P.f Positive	133	0	133	Sensitivity:100.00% (97.19-100.00%)
	P.f Negative	1	375	376	Specificity:99.73% (98.53-99.99%)

*Specimen type used for SD Bioline: venous whole blood; Specimen type used for Wondfo: fingerstick whole blood.

2.2 Comparison with PCR assay

Place of Evaluation	PCR	Wondfo Malaria P.f (HRP2/pLDH) Test			
		Positive	Negative	Total	Test Result (95% CI)
Cote d'Ivoire	P.f Positive	117	1	118	Sensitivity: 99.15% (95.37%-99.98%)
	P.f Negative	67	353	420	Specificity: 84.05% (80.19%-87.42%)

*Specimen type used for PCR: venous whole blood; Specimen type used for Wondfo: fingerstick whole blood.

2.3 Comparison among different specimen types

Place of Evaluation	Wondfo Malaria P.f (HRP2/pLDH) Test	SD Bioline		Test Result (95% CI)
		Venous whole blood		
		Positive	Negative	
Cameroon	Venous whole blood	Positive	36	0	Sensitivity: 100% (87.13%-100.00%)
		Negative	0	30	Specificity: 100% (88.43%-100.00%)
	Fingerstick whole blood	Positive	36	0	Sensitivity: 100% (87.13%-100.00%)
		Negative	0	30	Specificity: 100% (88.43%-100.00%)

*Specimen type used for SD Bioline: venous whole blood; Specimen type used for Wondfo: venous whole blood and fingerstick whole blood.

Analytical performance study

1. The repeatability and reproducibility of Wondfo Malaria P.f (HRP2/pLDH) Test are of good performance demonstrated by in-house panel according to CLSI EP-05 (A3).100% reproducibility was observed in studies within run, between run, between lots, and between sites and operators.
2. The following potential interfering substances have no impact on Wondfo Malaria P. f (HRP2/ pLDH) Test.

No.	Type	Interfering substances
1	Endogenous	HAMA
2		Rheumatoid factors
3		Anti-dsDNA antibody
4		Anti-cardiolipin antibody IgG
5		Anti-cardiolipin antibody IgM
6		Rheumatoid factors
7		IgG
8		IgM
9		Albumin
10		total bilirubin
11		Triglyceride
12		Human Chorionic Gonadotropin
13		Cholesterol
14		Low density lipoprotein
15		Haemoglobin
16		Direct bilirubin
17	Exogenous	Chloroquine Phosphate
18		Artesunate
19		Amoxicillin
20		Caffeine
21		Doxycycline Hyclate
22		Erythromycin
23		Ibuprofen
24		Piperaquine
25		Mebendazole
26		Tribendimidine
27		Sildenafil
28		Rifampicin
29		Aspirin
30		Paracetamol
31		Ethanol
32		Caffeine

3. The following potential cross-reacting pathogens have no impact on Wondfo Malaria P.f (HRP2/ pLDH) Test.

No.	Type	Cross-reacting substances
1	Antigen	Brucella sp.
2		HBsAg
3		Dengue Virus Type 1
4		HIV-1
5		HCV
6		Syphilis
7		Leishmania sp.
8		Leptospira sp.
9		M. tuberculosis
10		Schistosoma sp.
11		Toxoplasma gondii
12		Plasmodium vivax
13		HAV
14		Measles
15		Influenza
16		Tick borne encephalitis
17	Antibody	Rubella-IgG
18		Dengue Virus IgG
19		Cytomegalovirus-IgG

4. The Limit of Detection of the Wondfo Malaria P.f (HRP2/pLDH) Test for P.f HRP2 (T1 line) and P.f pLDH (T2 line) is 15.63 IU/mL (NIBSC 16/376 1:128) and 31.25 IU/mL (NIBSC 16/376 1:64), respectively.

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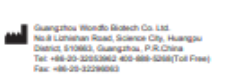
SYMBOLS KEY



MANUFACTURER INFORMATION

Guangzhou Wondfo Biotech Co. Ltd.
No.8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China
Tel: +86-20-32053962 400-888-5268(Toll Free)
Fax: +86-20-22296863
E-mail: global@wondfo.com.cn
Website: en.wondfo.com

Please contact the manufacturer or your local distributor if you have any questions about the product.

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IFU Version Information		
Rev. A6 (Valid version)	Ref.: 2024/805	Minor changes in the limitations of the test and changes in the performance characteristics section.
Rev. A5	Ref.: 2023/1222	Supplementation of intended testing population in intended use section and changes in the performance characteristics section.
Rev. A4	Ref.: 2021/1216	Supplementation of clinical data in performance characteristics section.
Rev. A3	Ref.: 2021/630	Adjustment of product configurations in kit components section.
Rev. A2	Ref.: 2021/618	Supplementation of clinical data in performance characteristics section
Rev. A1	Ref.: 2020/1127	Original version.