

WHO Prequalification of In Vitro Diagnostics PUBLIC ASSESSMENT REPORT

Product: Wondfo Malaria P.f (HRP2/pLDH) Test WHO reference number: PQDx 0651-004-00

Wondfo Malaria P.f (HRP2/pLDH) Test with product codes W037P0041, W037P0022, W037P0028, W037P0030, W037P0024, W037P0033, W037P0035, and W037P0037, manufactured by Guangzhou Wondfo Biotech Co., Ltd, Rest-of-World version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 30 July 2024.

Summary of WHO prequalification assessment for the Wondfo Malaria P.f (HRP2/pLDH) Test

	Date	Outcome
Prequalification listing	30 July 2024	listed
Dossier assessment	29 July-2024	MR
Site inspection(s) of quality management system	13 February 2024	MR
Product performance evaluation	Quarter 4 2022	MR

MR: Meets Requirements

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Reason for amendment and change request reference, where applicable.	Date of report amendment
2.0	<p>The manufacturer has proposed the following changes:</p> <ol style="list-style-type: none"> 1. Changes to the accessories, including: <ul style="list-style-type: none"> • replacement of lancet supplier; • change to the manufacturing address of the inverted cup supplier; 2. Addition of languages to IFU and labels. 3. Change to the pack size of the test kit (addition of 	19 March 2026

	configuration 10 tests/kit)(PQC-IVD-2025-0067).	
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Intended use

According to the intended use claim from Guangzhou Wondfo Biotech Co., Ltd, “*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.”

Test kit contents

Component	10 Test (T) (W037P0041)	25 T (W037P0022)	40 T (W037P0024)	25 T (W037P0028)	25 T (W037P0030)	40 T (W037P0033)	40 T (W037P0035)	100 T (W037P0037)
Cassette (pieces (pcs))	10	25	40	25	25	40	40	100
Instructions	1	1	1	1	1	1	1	1
Buffer	1x5mL/bottle	25x0.3 mL/vial	40x0.3 mL/vial	2x5 mL/bottle	2x5 mL/bottle	4x5 mL/bottle	4x5 mL/bottle	8x5 mL/bottle
Quick guide (pcs)	/	25 pouches, each containing one quick guide:	40 pouches, each containing one quick guide:	/	/	/	/	/
Inverted cup (pcs)	10	one inverted cup,	one inverted cup,	25	25	40	40	100
Alcohol prep pad (pcs)	10	one alcohol prep pad,	one alcohol prep pad,	25	25	40	40	100
Sterile lancet (pcs)	10	one sterile lancet.	one sterile lancet.	25	/	40	/	100
Blood lancet for single use (pcs)	/	/	/	/	25	/	40	/

Items required but not provided

- Timer
- Protective gloves
- Specimen and test waste container

- 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

The test kit must be stored between 1 and 40 °C.

Shelf-life upon manufacture¹

24 months.

Warnings/limitations

Refer to the current version of the manufacturer's instructions for use attached to this public assessment report.

The WHO Global Malaria Programme recommends the use of tests detecting pLDH and a panel detection of at least 75% on the panel of non-HRP2 expressing specimens in areas with high prevalence of *pfhrp2/3* gene deletions². This test does not meet these criteria and is not recommended for use in such settings.

Dossier assessment

Guangzhou Wondfo Biotech Co., Ltd submitted a product dossier for the Wondfo Malaria P.f (HRP2/pLDH) Test as per the "Instructions for compilation of a product dossier" (PQDx_018). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO. The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 29 July 2024.

Based on the product dossier screening and assessment findings, the product dossier for the Wondfo Malaria P.f (HRP2/pLDH) Test meets WHO prequalification requirements.

Manufacturing site inspection

¹ The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

² <https://iris.who.int/bitstream/handle/10665/258972/WHO-HTM-GMP-2017.18-eng.pdf?sequence=1>

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer's quality management system (QMS) and manufacturing practices are in alignment with:

- (i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
- (ii) the manufacturer's own documented procedures and quality requirements; and
- (iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO's Public Inspection Reports are accessible at:

<https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports>

Based on the site inspection and corrective action plan review, the quality management system for the Wondfo Malaria P.f (HRP2/pLDH) Test meets WHO prequalification requirements.

Product performance evaluation

Wondfo Malaria P.f (HRP2/pLDH) Test was evaluated by the Centers for Disease Control and Prevention on behalf of WHO in the fourth quarter of 2022, according to protocol PQDx_317, version 3.1.

Clinical performance evaluation

Wondfo Malaria P.f (HRP2/pLDH) Test was evaluated against a *Plasmodium falciparum* cultured line panel, *P. falciparum* wild type parasite panel, *P. vivax* wild type parasite panel, *hrp2/3* deletion panel, a parasite-negative panel (including clean negatives from afebrile donors and specimens with possible cross-reactants), and the WHO International standard for *P. falciparum* antigens.

Performance characteristics			
	<i>P. falciparum</i>	<i>P. vivax</i>	Pf – <i>hrp2</i> deletion panel
Panel detection score [#] at 200 parasites/μL	93/100, 93.0 %	NA	21/60, 35.0%
Proportion detected by line at 200 parasites/μL	HRP2 line: 98.0% Pf-pLDH line: 55.0% (N=400)	NA	HRP2 line: 16.7% Pf-pLDH line: 52.5% (N=240)
False positive results %	All negative specimens: 0/200, 0.0% Of which, clean negative specimens: 0/104, 0% No false Pf result on the <i>P. vivax</i> specimens at 200 and 2000 parasites/μL		
Invalid rate %	0/1322, 0.0 %		

(N= 1322)	
Inter-reader variability on the wild-type and negative panels % (N= 1010)	HRP2 test line: 1/1010, 0.1 % Pf-pLDH test line: 166/1010, 16.4%
Lowest concentration of HRP2/pLDH detected using the 1 st WHO International standard for Pf antigens (NIBSC code: 16/376)*	HRP2 test line: Lot A: 7.8 IU/mL Lot B: 3.9 IU/mL Pf-pLDH test line: Lot A: 15.6 IU/mL Lot B: 15.6 IU/mL

The panel detection score is the proportion of specimens at a specified concentration that gave positive results in all 4 tests performed with this specimen (2 tests on each of 2 lots).

* Not applicable for assays evaluated in WHO product testing of RDTs for malaria antigen detection.

Operational characteristics and ease of use

This assay does not require laboratory equipment and can be performed in laboratories with limited facilities or in non-laboratory settings.

The assay was found easy to use by the operators performing the evaluation.

However, the operators noted that 383/1010 (37.9 %) of the tests performed on the wild-type and negative panels showed anomalies (234 with incomplete clearing, 38 with red background, 51 with red background obscuring test line, 58 with patchy line, 1 with strip misplaced, and 1 with failed migration).

Key operational characteristics	
Specimen type and volume	5 µL of fingerstick whole blood or venous whole blood collected into a blood collection tube with anticoagulant (EDTA, sodium citrate, or heparin sodium)
Number of steps*	2 steps in total 1 step with specimen transfer device (precision pipette was used during the evaluation)
Time to result	15 minutes
Endpoint stability (interval)	15 minutes (the test can be read between 15 and 30 minutes after addition of diluent)
Internal QC	Yes, reagent addition control

* Definition: each action required to obtain a result (excluding specimen collection, device preparation – opening the pouch), e.g. for RDTs: add specimen, add buffer (2 steps).

Based on these results, the performance evaluation for the Wondfo Malaria P.f (HRP2/pLDH) Test meets the WHO prequalification requirements.

Labelling review

The labelling submitted for the Wondfo Malaria P.f (HRP2/pLDH) Test was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

Controlled Labelling References

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.	Applicable Catalog No.	
Outer box artwork	Box artwork	A3	2024/06/25	DLA-W037(2)-01-01	W037P0022	
				DLA-W037(2)-01-02	W037P0024	
				DLA-W037(2)-01-03	W037P0028	
				DLA-W037(2)-01-04	W037P0030	
				DLA-W037(2)-01-05	W037P0033	
				DLA-W037(2)-01-06	W037P0035	
				DLA-W037(2)-01-07	W037P0037	
		A1	2025/06/06	DLA-W037(2)-01-08	W037P0041	
Outer box label	Box label	A3	2025/06/06	DLB-W037(2)-01-01	W037P0022	
				DLB-W037(2)-01-02	W037P0024	
				DLB-W037(2)-01-03	W037P0028	
				DLB-W037(2)-01-05	W037P0033	
				DLB-W037(2)-01-07	W037P0037	
				A4	DLB-W037(2)-01-04	W037P0030
				DLB-W037(2)-01-06	W037P0035	
		A1	DLB-W037(2)-01-08	W037P0041		
Pouch / Device label	Pouch	A3	2024/06/25	DLC-W037(2)-01-01	All	
Accessory labeling	Accessory pouch	A3	2025/06/06	DAV-W037(2)-01-01	W037P0022	
				DAV-W037(2)-01-02	W037P0024	
Accessory labeling (buffer)	Buffer label	A2	2024/06/25	DLD-W037(2)-01-01	W037P0022	
				DLD-W037(2)-01-02	W037P0024	
				DLD-W037(2)-01-03	W037P0028	
					W037P0030	
					W037P0033	
					W037P0035	
					W037P0037	

					W037P0041
Accessory labeling (inverted cup)	Dropper label	A3	2025/06/06	DLX-W037(2)-01-01	W037P0028
		A1		DLX-W037(2)-01-02	W037P0037
		A3		DLX-W037(2)-01-03	W037P0041
				DLX-W037(2)-01-04	W037P0030
				DLX-W037(2)-01-05	W037P0033
Accessory labeling (lancet labels)	Lancet	A2	2024/12/11	DLV-W037(2)-01-01	W037P0035
				DLV-W037(2)-01-02	W037P0028
		A0	2025/07/01	DLV-W037(2)-01-03	W037P0037
				DLV-W037(2)-01-04	W037P0033
				DLV-W037(2)-01-05	W037P0030
A1	2025/06/06	DLV-W037(2)-01-05	W037P0035		
Quick Guide	Quick Guide	A2	2024/9/26	DLI-W037(2)-01-01	W037P0041
					W037P0022
Instructions for Use (IFU)	IFU	A7	2025/6/6	IFU-W037(2)-01-01	W037P0024
					All

Labels

Wondfo Malaria P.f (HRP2/pLDH) Test



CONTENTS:

1. 25 Individual pouches, each containing:
 - Test cassette
 - Desiccant pouch
2. 25 Vials of P.f buffer (0.3mL/vial)
3. 1 Instruction for use
4. 25 Alcohol prep pads
5. 25 Sterile lancets
6. 25 Inverted cups
7. 25 Quick guides

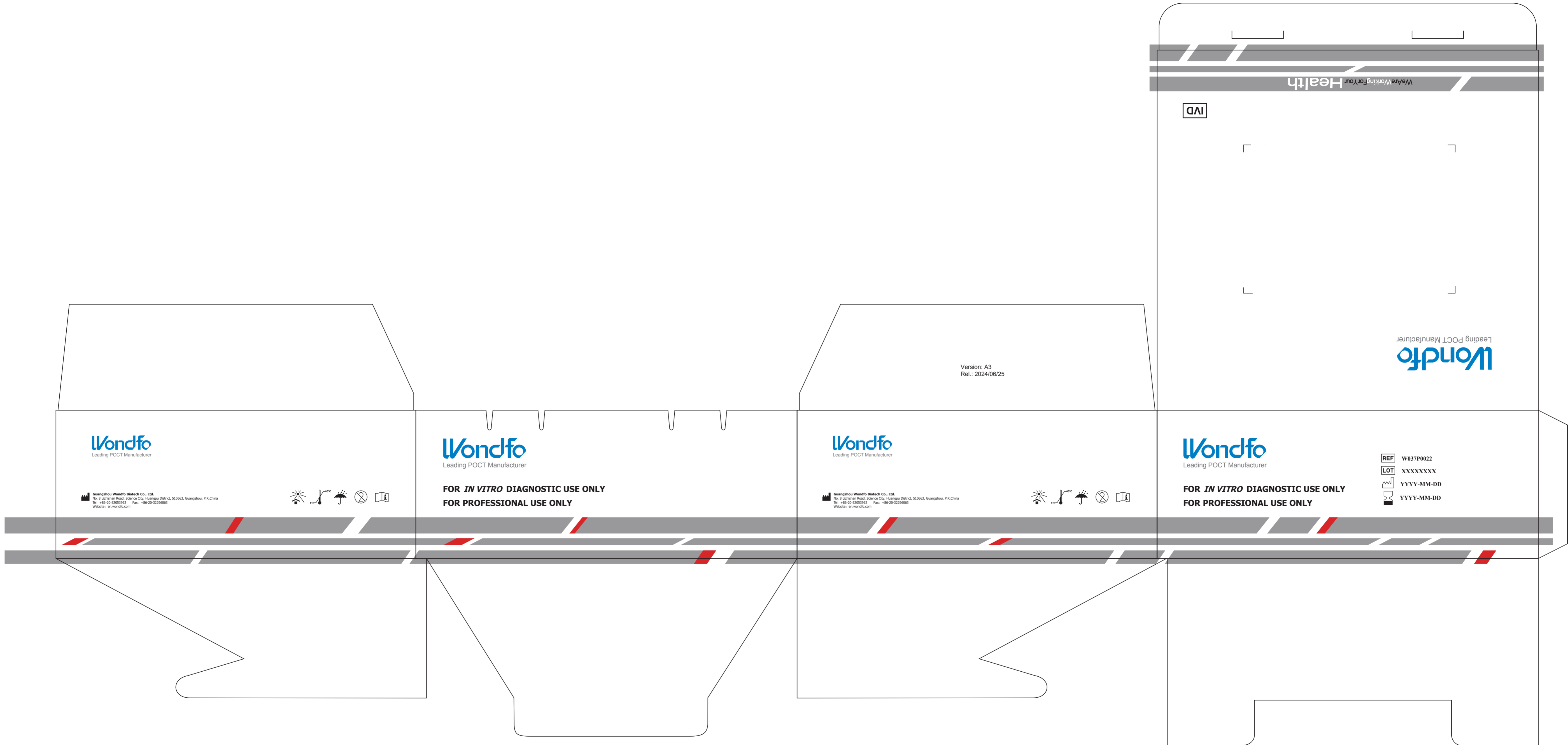
CONTENU :

1. 25 sachets individuels, chacun contenant :
 - Cassette de test
 - Sachet déshydratant
2. 25 fioles de solution tampon (0.3 mL/fiole)
3. 1 Notice d'utilisation
4. 25 Tampons alcoolisés
5. 25 Lancettes stériles
6. 25 Coupelles inversées
7. 25 Guides rapides

CONTEÚDO:

1. 25 Bolsas individuais, cada uma contendo:
 - Cassete de teste
 - Bolsa dessecante
2. 25 Frascos de buffer P.f (0,3mL/frasco)
3. 1 Instrução de utilização
4. 25 Compressas de álcool
5. 25 Lancetas esterilizadas
6. 25 Copos invertidos
7. 25 Guias rápidos

Version: A3
Rel.: 2025/06/06



Wondfo
Leading POCT Manufacturer

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REF	W037P0022
LOT	XXXXXXXX
EXP	YYYY-MM-DD
EXP	YYYY-MM-DD

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We're Working For Your Health

IVD

距开口15mm



Wondfo
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Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX

 YYYY-MM-DD

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Website: en.wondfo.com

10mm



Wondfo

Accessories pouch

CONTENT:	CONTENU :	CONTEÚDO :
1 Quick guide	1 Guides rapides	1 Guia rápido
1 Inverted cup	1 Coupelles inversées	1 Copo invertido
1 Alcohol prep pad	1 Tampons alcoolisés	1 Compressa com álcool
1 Sterile lancet	1 Lancettes stériles	1 Lanceta esterilizada



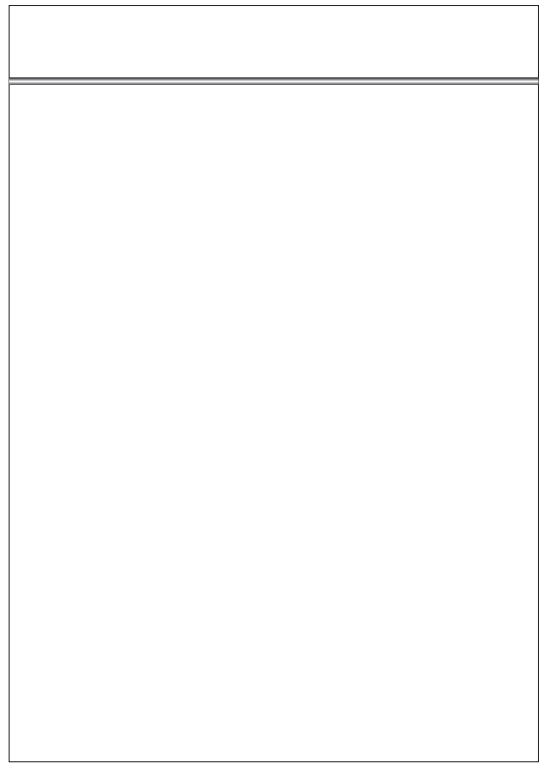




Rev.A3
Rel.:2025/06/06

14.798mm

13mm

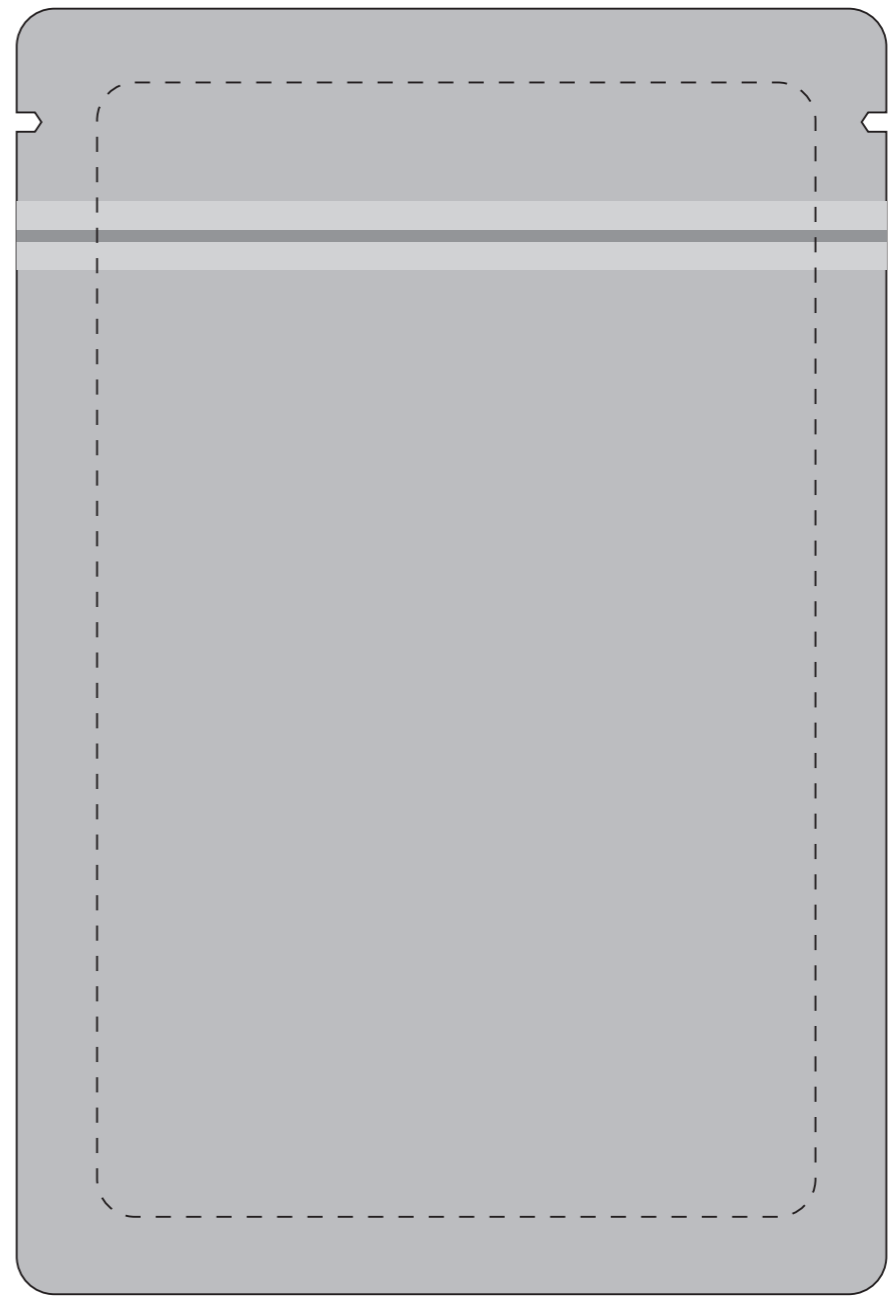
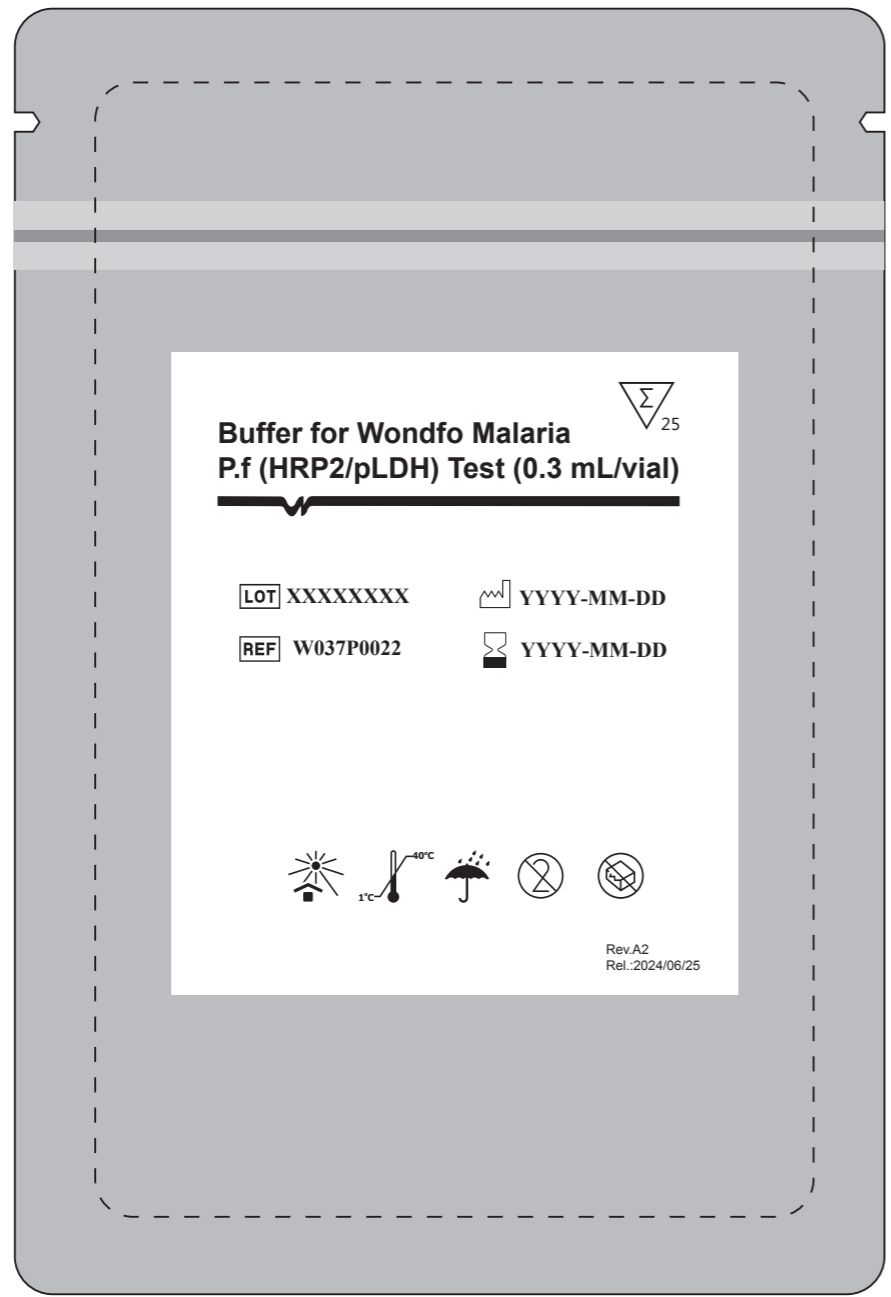


100mm

70mm

撕口位置
15mm

拉链位置
30mm



↑
三边封；供应商预留开口

封边
10mm

Wondfo Malaria P.f (HRP2/pLDH) Test



CONTENTS:

1. 40 Individual pouches, each containing:
 - Test cassette
 - Desiccant pouch
2. 40 Vials of P.f buffer (0.3mL/vial)
3. 1 Instruction for use
4. 40 Alcohol prep pads
5. 40 Sterile lancets
6. 40 Inverted cups
7. 40 Quick guides

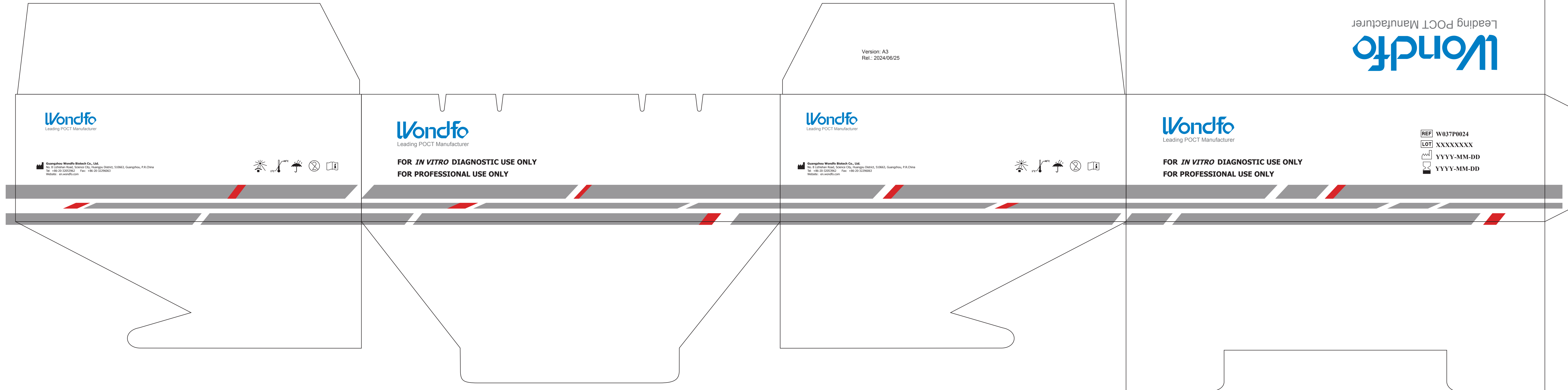
CONTENU :

1. 40 sachets individuels, chacun contenant :
 - Cassette de test
 - Sachet déshydratant
2. 40 fioles de solution tampon (0.3 mL/fiole)
3. 1 Notice d'utilisation
4. 40 Tampons alcoolisés
5. 40 Lancettes stériles
6. 40 Coupelles inversées
7. 40 Guides rapides

CONTEÚDO:

1. 40 bolsas individuais, cada uma contendo:
 - Cassete de teste
 - Bolsa dessecante
2. 40 frascos de buffer P.f (0,3mL/frasco)
3. 1 Instruções de utilização
4. 40 compressas com álcool
5. 40 lancetas esterilizadas
6. 40 Copos invertidos
7. 40 Guias rápidos

Version: A3
Rel.:2025/06/06



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REF: W037P0024
LOT: XXXXXXXX
YYMM-DD
YYMM-DD

We Are Working For Your Health

距开口 15mm



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Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX

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REF W037P0024

YYYY-MM-DD

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10mm



Wondfo

Accessories pouch

CONTENT:	CONTENU :	CONTEÚDO :
1 Quick guide	1 Guides rapides	1 Guia rápido
1 Inverted cup	1 Coupelles inversées	1 Copo invertido
1 Alcohol prep pad	1 Tampons alcoolisés	1 Compressa com álcool
1 Sterile lancet	1 Lancettes stériles	1 Lanceta esterilizada



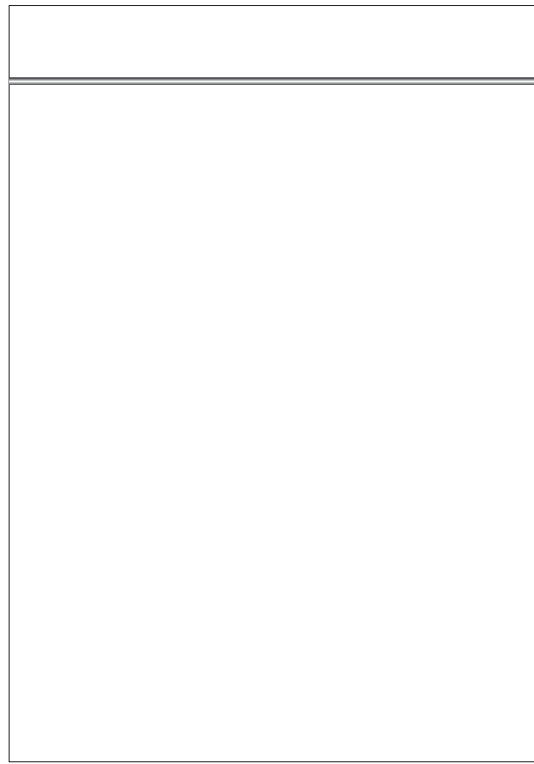




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Rel.:2025/06/06

14.798mm

13mm

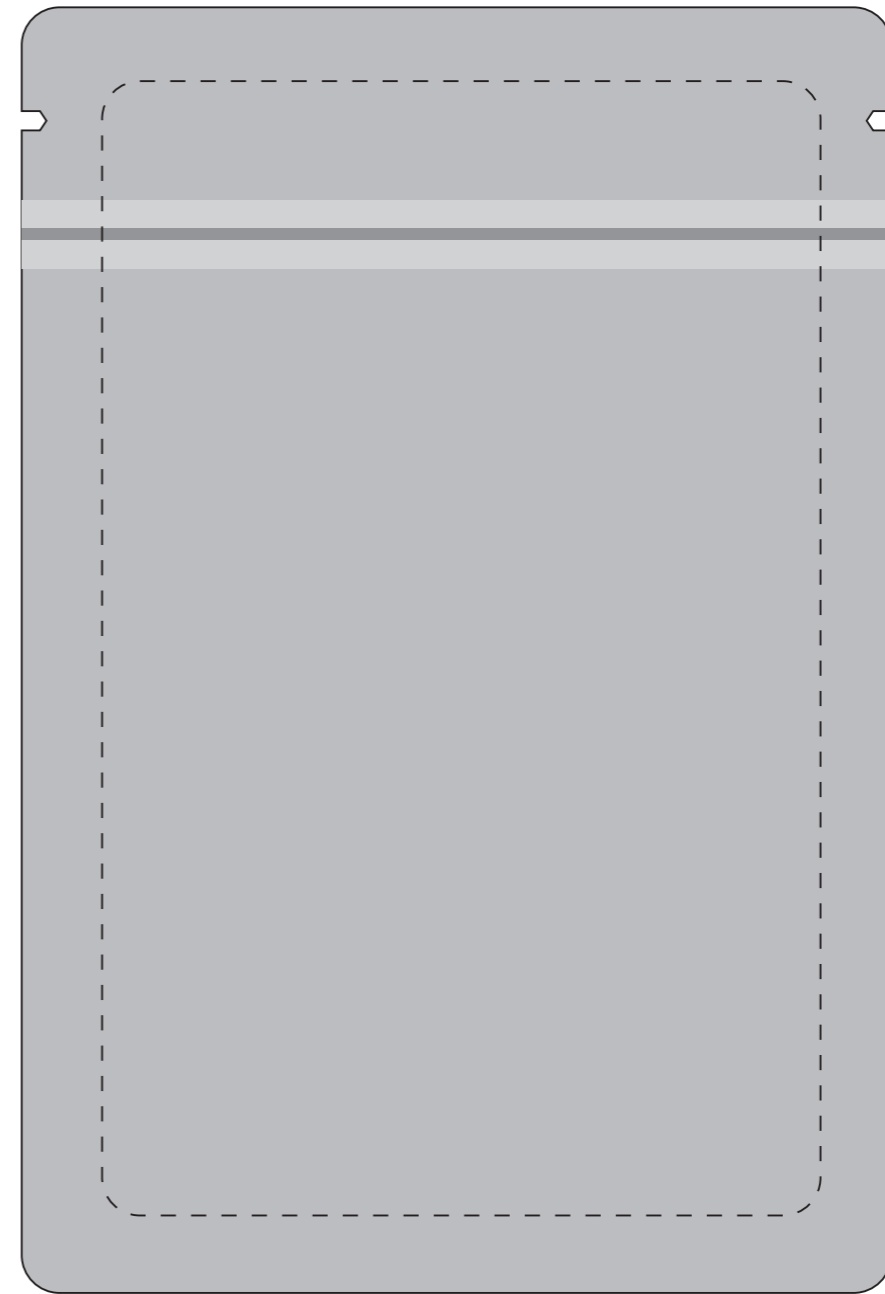
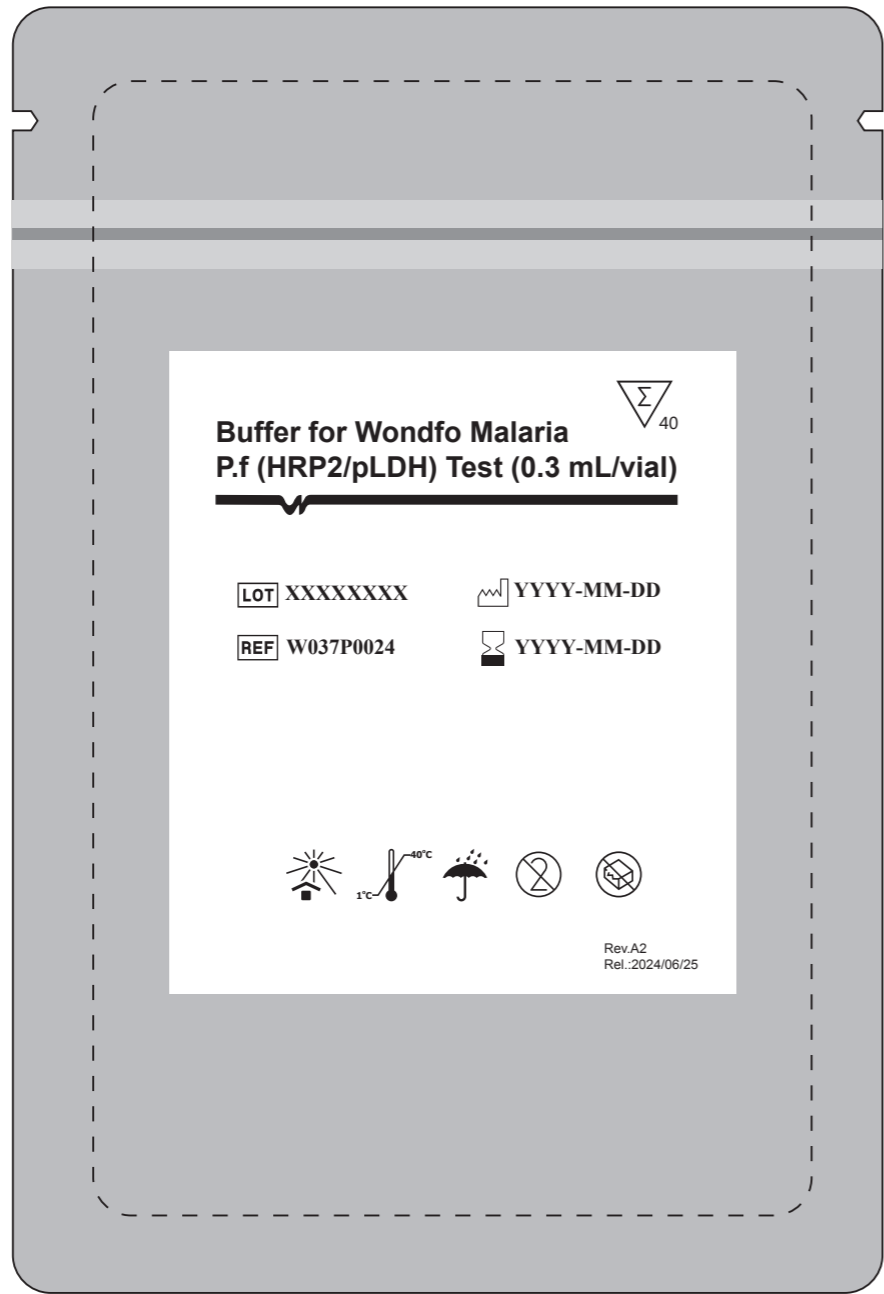


100mm

70mm

撕口位置
15mm

拉链位置
30mm



三边封；供应商预留开口
封边
10mm

Wondfo Malaria P.f (HRP2/pLDH) Test



CONTENTS:

1. 25 Individual pouches, each containing:
 - Test cassette
 - Desiccant pouch
2. 2 Bottles of buffer (5mL/bottle)
3. 1 Instruction for use
4. 25 Alcohol prep pads
5. 25 Sterile lancets
6. 25 Inverted cups

CONTENU :

1. 25 sachets individuels, chacun contenant :
 - Cassette de test
 - Sachet déshydratant
2. 2 Flacons de solution tampon (5 mL/flacon)
3. 1 Notice d'utilisation
4. 25 Tampons alcoolisés
5. 25 Lancettes stériles
6. 25 Coupelles inversées

CONTEÚDO:

1. 25 bolsas individuais, cada uma contendo:
 - Cassete de teste
 - Bolsa dessecante
2. 2 Garrafas de buffer (5mL/garrafa)
3. 1 Instruções de utilização
4. 25 Compressas com álcool
5. 25 Lancetas esterilizadas
6. 25 Copos invertidos

Version: A3
Rel.: 2025/06/06

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REF W037P0028
LOT XXXXXXXX
YYYY-MM-DD
YYYY-MM-DD

We Are Working For Our Health

IVD

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距开口15mm



Wondfo
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Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX

⌚ YYYY-MM-DD

REF W037P0028

📄 YYYY-MM-DD

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IVD



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Website: en.wondfo.com

Sterile Lancet

25
pcs



Rev. A2
Rel.: 2024/12/11



Beijing Ruicheng Medical Supplies Co., Ltd.
Building 5, No. 8, Yanqi West Road, Yanqi
Economic Development Zone, Huairou District
101407 Beijing P.R. China



Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The
Hague, Netherlands.



STERILE R



LOT



Manufactured for Wondfo Biotech by Beijing Ruicheng Medical Supplies Co., Ltd.



Inverted cup

 Foshan Yuyang Medical Instrument Co.,Ltd.
Room 501,5th Floor, Building B, No. 1 Kesheng Road,Lishui
Town,Nanhai District, Foshan City,Guangdong, China

LOT



Manufactured for Wondfo Biotech by
Foshan Yuyang Medical Instrument Co.,Ltd.

Language: English
Rev.A3 Ref.20250608



size:38*20mm

**Buffer for Wondfo Malaria
P.f (HRP2/pLDH) Test**

Lot: XXXXXXXX

Ref: W037P0028

Exp: YYYY-MM-DD

Vol:5ml

Store at:1-40°C

Version:A2

Rel.:2024/06/25

size:38*20mm

Wondfo Malaria P.f (HRP2/pLDH) Test



CONTENTS:

1. 25 Individual pouches, each containing:
 - Test cassette
 - Desiccant pouch
2. 2 Bottles of buffer (5mL/bottle)
3. 1 Instruction for use
4. 25 Alcohol prep pads
5. 25 Blood lancets for single use
6. 25 Inverted cups

CONTENU :

1. 25 sachets individuels, chacun contenant :
 - Cassette de test
 - Sachet déshydratant
2. 2 Flacons de solution tampon (5 mL/flacon)
3. 1 Notice d'utilisation
4. 25 Tampons alcoolisés
5. 25 Lancettes à aiguille retractable
6. 25 Coupelles inversées

CONTEÚDO:

1. 25 Bolsas individuais, cada uma contendo:
 - Cassete de teste
 - Bolsa dessecante
2. 2 Garrafas de buffer (5mL/garrafa)
3. 1 Instruções de utilização
4. 25 Compressas com álcool
5. 25 Lancetas hemocráticas descartáveis
6. 25 Copos invertidos

Version: A4
Rel.: 2025/06/06

Wondfo
Leading POCT Manufacturer

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Leading POCT Manufacturer

FOR *IN VITRO* DIAGNOSTIC USE ONLY
FOR PROFESSIONAL USE ONLY

FOR *IN VITRO* DIAGNOSTIC USE ONLY
FOR PROFESSIONAL USE ONLY



REF W037P0030
LOT XXXXXXXX
YYYY-MM-DD
YYYY-MM-DD

Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China
Tel: +86-20-32293962 Fax: +86-20-32296683
Website: en.wondfo.com

Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China
Tel: +86-20-32293962 Fax: +86-20-32296683
Website: en.wondfo.com

Version: A3
Rel.: 2024/06/25

WeAreWorkingForOur Health

IVD

Wondfo
Leading POCT Manufacturer

距开口15mm



Wondfo
Leading POCT Manufacturer

Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX

 YYYY-MM-DD

REF W037P0030

 YYYY-MM-DD

Version: A3

Rel.: 2024/06/25

FOR IN VITRO DIAGNOSTIC USE ONLY

Wondfo

IVD



Guangzhou Wondfo Biotech Co., Ltd.

No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China

Tel: +86-20-32053962 Fax: +86-20-32296063

Website: en.wondfo.com

Lancet (21G)

Blood Lancet for Single Use

25
pcs



Hebei Xinle Sci&Tech CO.,LTD
No. 2, Xingye Street, Xinle City, 050700 Shijiazhuang City,
Hebei province, PEOPLE'S REPUBLIC OF CHINA
Tel:0086-311-88655818 Fax:0086-311-88655819

Rev.A0
Rel.:2025/07/01

MD STERILE R

EU REP

Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg,Germany
Tel:0049-40-2513175 Fax:0049-40-255726
E-mail:shholding@hotmail.com

⊗ ⊗ CE 0123

Model: XLII-2118

LOT



Manufactured for Wondfo Biotech by Hebei Xinle Sci&Tech CO.,LTD

www.hbxinle.com

Inverted cup

 Foshan Yuyang Medical Instrument Co.,Ltd.
Room 501,5th Floor, Building B, No. 1 Kesheng Road,Lishui
Town,Nanhai District, Foshan City,Guangdong, China

LOT



Manufactured for Wondfo Biotech by
Foshan Yuyang Medical Instrument Co.,Ltd.

Language: English
Rev.A3 Ref.20250608



size:38*20mm

**Buffer for Wondfo Malaria
P.f (HRP2/pLDH) Test**

Lot: XXXXXXXX

Ref: W037P0030

Exp: YYYY-MM-DD

Vol:5ml

Store at:1-40°C

Version:A2

Rel.:2024/06/25

size:38*20mm

Wondfo Malaria P.f (HRP2/pLDH) Test



CONTENTS:

1. 40 Individual pouches, each containing:
 - Test cassette
 - Desiccant pouch
2. 4 Bottles of buffer (5mL/bottle)
3. 1 Instruction for use
4. 40 Alcohol prep pads
5. 40 Sterile lancets
6. 40 Inverted cups

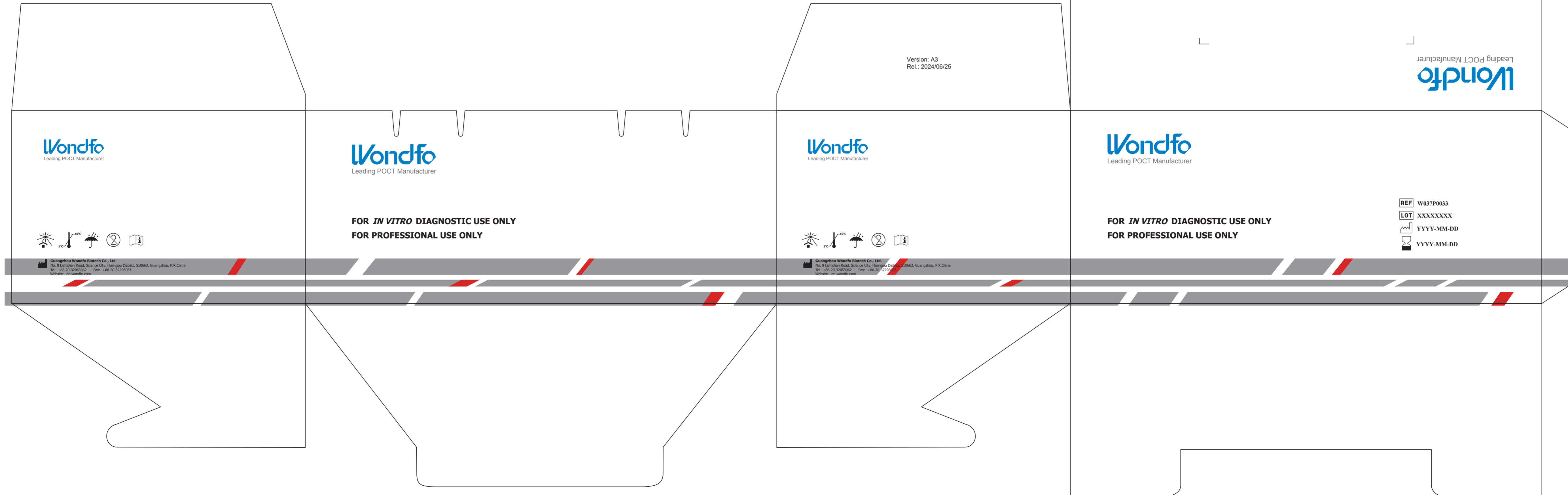
CONTENU :

1. 40 sachets individuels, chacun contenant :
 - Cassette de test
 - Sachet déshydratant
2. 4 Flacons de solution tampon (5 mL/flacon)
3. 1 Notice d'utilisation
4. 40 Tampons alcoolisés
5. 40 Lancettes stériles
6. 40 Coupelles inversées

CONTEÚDO:

1. 40 Bolsas individuais, cada uma contendo:
 - Cassete de teste
 - Bolsa dessecante
2. 4 Garrafas de buffer (5ml/garrafa)
3. 1 Instruções de utilização
4. 40 Compressas com álcool
5. 40 Lancetas esterilizadas
6. 40 Copos invertidos

Version: A3
Rel.: 2025/06/06



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FOR PROFESSIONAL USE ONLY

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Guangzhou Wondfo Biotech Co., Ltd.
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Website: en.wondfo.com

Guangzhou Wondfo Biotech Co., Ltd.
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Tel: +86-20-32053962 Fax: +86-20-32295063
Website: en.wondfo.com

Version: A3
Rel.: 2024/06/25

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Leading POCT Manufacturer

We're Working For Your Health

IVD

REF	W037P0033
LOT	XXXXXXXX
	YYYY-MM-DD
	YYYY-MM-DD

距开口15mm



Wondfo
Leading POCT Manufacturer

Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX

YYYY-MM-DD

REF W037P0033

YYYY-MM-DD

Version: A3

Rel.: 2024/06/25

FOR IN VITRO DIAGNOSTIC USE ONLY

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IVD



Guangzhou Wondfo Biotech Co., Ltd.

No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China

Tel: +86-20-32053962 Fax: +86-20-32296063

Website: en.wondfo.com

Sterile Lancet

40
pcs



Rev. A2
Rel.: 2024/12/11



Beijing Ruicheng Medical Supplies Co., Ltd.
Building 5, No. 8, Yanqi West Road, Yanqi
Economic Development Zone, Huairou District
101407 Beijing P.R. China



Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The
Hague, Netherlands.

CE

0197

STERILE R




LOT



Manufactured for Wondfo Biotech by Beijing Ruicheng Medical Supplies Co., Ltd.



Inverted cup

 Foshan Yuyang Medical Instrument Co., Ltd.
Room 501, 5th Floor, Building B, No. 1 Kesheng Road, Lishui
Town, Nanhai District, Foshan City, Guangdong, China

LOT



Manufactured for Wondfo Biotech by
Foshan Yuyang Medical Instrument Co., Ltd.

Language: English
Rev A3 (Rev. 2025/06/06)



size:38*20mm

**Buffer for Wondfo Malaria
P.f (HRP2/pLDH) Test**

Lot: XXXXXXXX

Ref: W037P0033

Exp: YYYY-MM-DD

Vol:5ml

Store at:1-40°C

Version:A2

Rel.:2024/06/25

size:38*20mm

Wondfo Malaria P.f (HRP2/pLDH) Test



CONTENTS:

1. 40 Individual pouches, each containing:
 - Test cassette
 - Desiccant pouch
2. 4 Bottles of buffer (5mL/bottle)
3. 1 Instruction for use
4. 40 Alcohol prep pads
5. 40 Blood lancets for single use
6. 40 Inverted cups

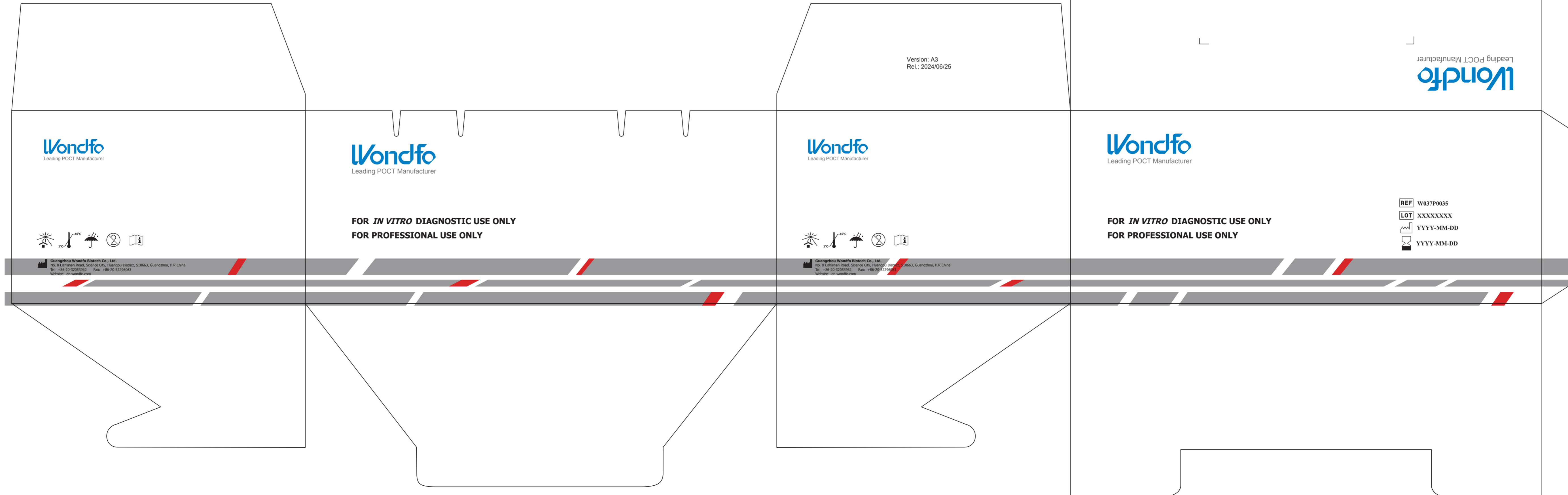
CONTENU :

1. 40 sachets individuels, chacun contenant :
 - Cassette de test
 - Sachet déshydratant
2. 4 Flacons de solution tampon (5 mL/flacon)
3. 1 Notice d'utilisation
4. 40 Tampons alcoolisés
5. 40 Lancettes à aiguille retractable
6. 40 Coupelles inversées

CONTEÚDO:

1. 40 bolsas individuais, cada uma contendo:
 - Cassete de teste
 - Bolsa dessecante
2. 4 garrafas de buffer (5 mL/garrafa)
3. 1 instrução de utilização
4. 40 compressas com álcool
5. 40 lancetas de sangue, descartáveis
6. 40 Copos invertidas

Version: A4
Rel.: 2025/06/06



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FOR *IN VITRO* DIAGNOSTIC USE ONLY
FOR PROFESSIONAL USE ONLY

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FOR PROFESSIONAL USE ONLY

Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lishiwan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China
Tel: +86-20-32053962 Fax: +86-20-32296063
Website: en.wondfo.com

Guangzhou Wondfo Biotech Co., Ltd.
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Tel: +86-20-32053962 Fax: +86-20-32296063
Website: en.wondfo.com

Version: A3
Rel.: 2024/06/25

We're Working For You
Health

IVD

Leading POCT Manufacturer
Wondfo

REF	W037P0035
LOT	XXXXXXXX
	YYYY-MM-DD
	YYYY-MM-DD

距开口15mm



Wondfo
Leading POCT Manufacturer

Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX

XXXX-XX-XX

REF W037P0035

XXXX-XX-XX

Version: A3

Rel.: 2024/06/25

FOR IN VITRO DIAGNOSTIC USE ONLY

Wondfo

IVD



Guangzhou Wondfo Biotech Co., Ltd.

No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China

Tel: +86-20-32053962 Fax: +86-20-32296063

Website: en.wondfo.com

Lancet (21G)

Blood Lancet for Single Use

40
pcs



Hebei Xinle Sci&Tech CO.,LTD
No. 2, Xingye Street, Xinle City, 050700 Shijiazhuang City,
Hebei province, PEOPLE'S REPUBLIC OF CHINA
Tel:0086-311-88655818 Fax:0086-311-88655819

Rev.A0
Rel.:2025/07/01

MD STERILE R

EU REP

Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg,Germany
Tel:0049-40-2513175 Fax:0049-40-255726
E-mail:shholding@hotmail.com

⊗ ⊗ CE 0123

Model: XLII-2118

LOT



Manufactured for Wondfo Biotech by Hebei Xinle Sci&Tech CO.,LTD

www.hbxinle.com

Inverted cup

 Foshan Yuyang Medical Instrument Co., Ltd.
Room 501, 5th Floor, Building B, No. 1 Kesheng Road, Lishui
Town, Nanhai District, Foshan City, Guangdong, China

LOT



Manufactured for Wondfo Biotech by
Foshan Yuyang Medical Instrument Co., Ltd.

Language: English
Rev A3 Ref: 2025/06/06



size:38*20mm

**Buffer for Wondfo Malaria
P.f (HRP2/pLDH) Test**

Lot: XXXXXXXX

Ref: W037P0035

Exp: YYYY-MM-DD

Vol:5ml

Store at:1-40°C

Version:A2

Rel.:2024/06/25

size:38*20mm

Wondfo Malaria P.f (HRP2/pLDH) Test



CONTENTS:

1. 100 Individual pouches, each containing:
 - Test cassette
 - Desiccant pouch
2. 8 Bottles of buffer (5mL/bottle)
3. 1 Instruction for use
4. 100 Alcohol prep pads
5. 100 Sterile lancets
6. 100 Inverted cups

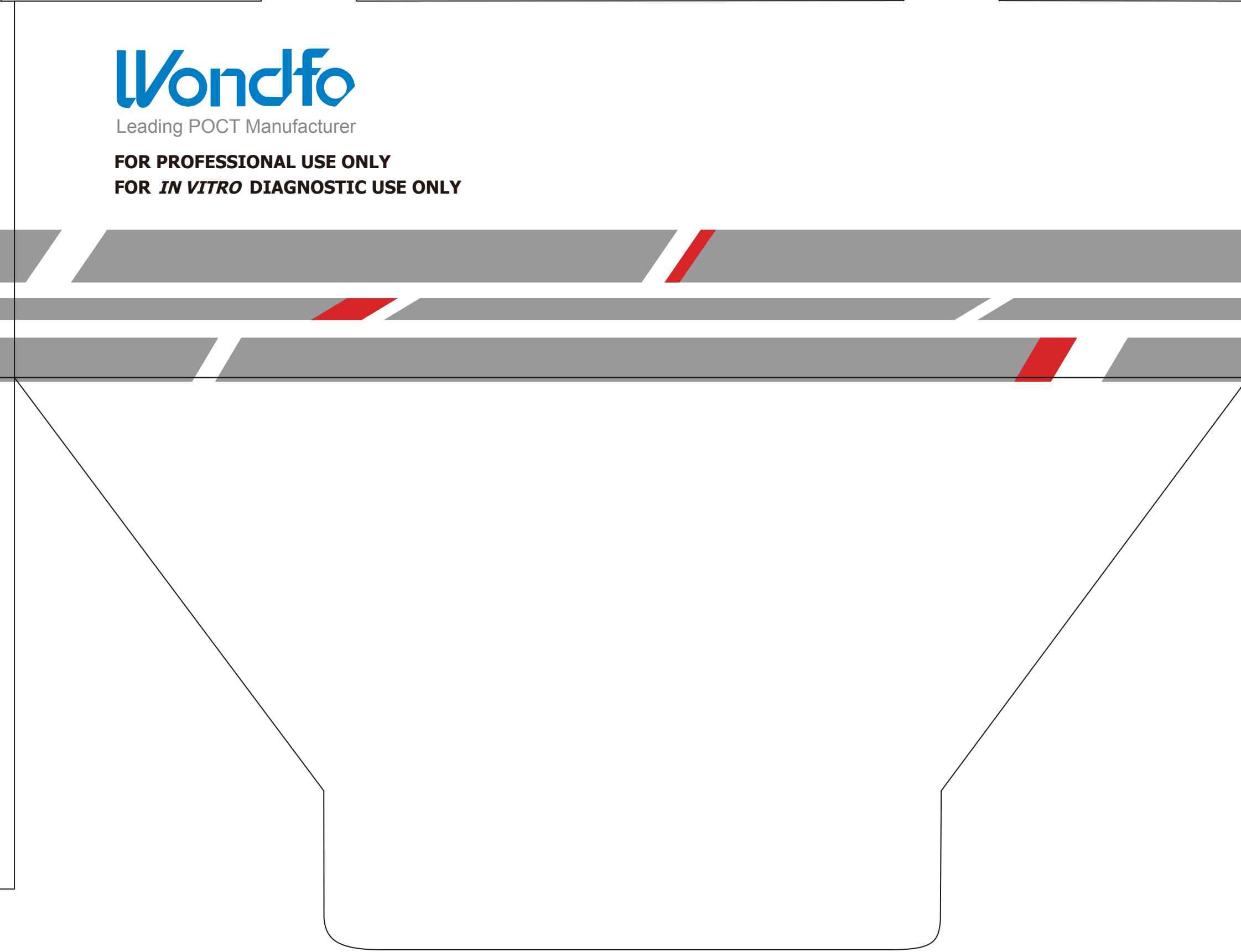
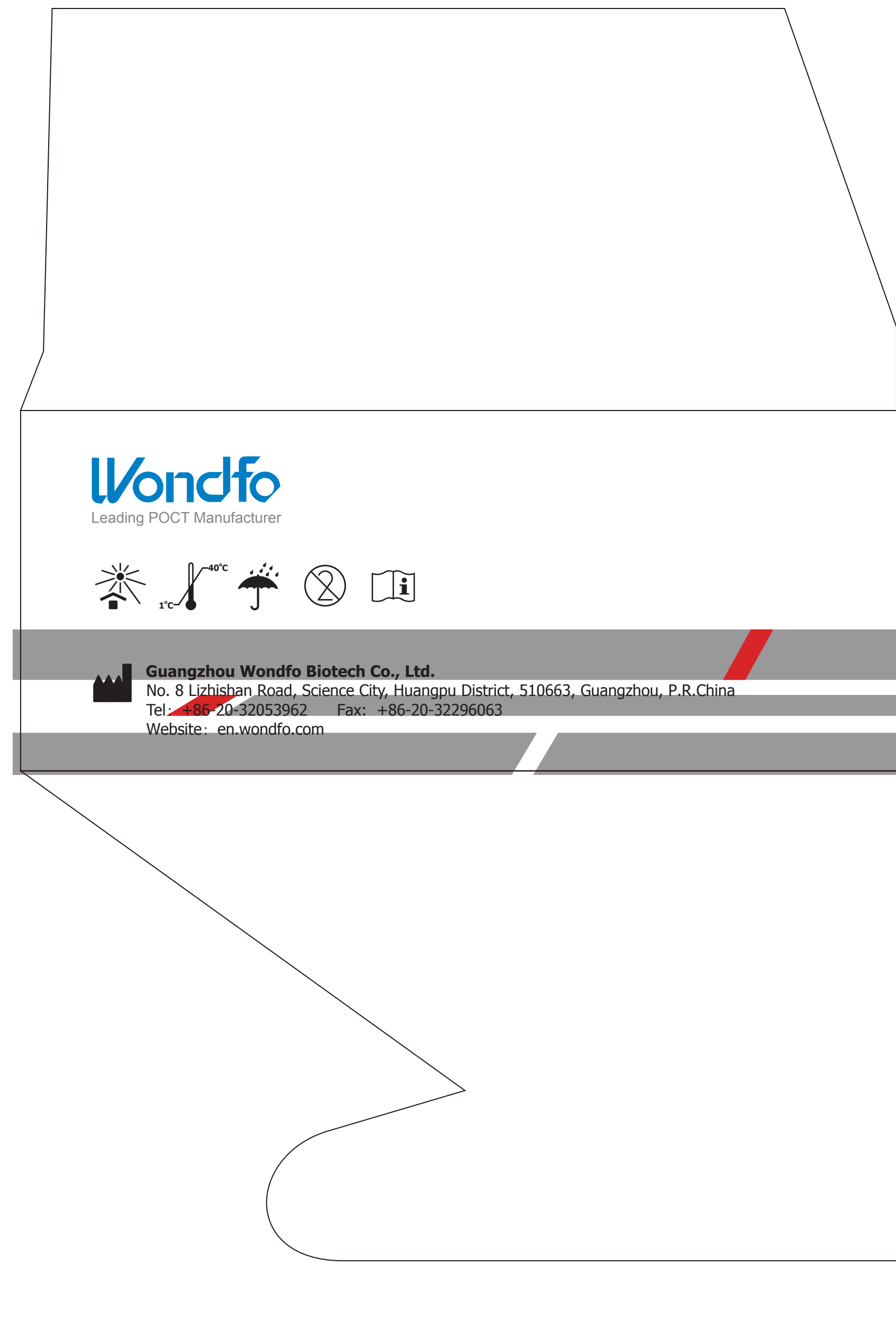
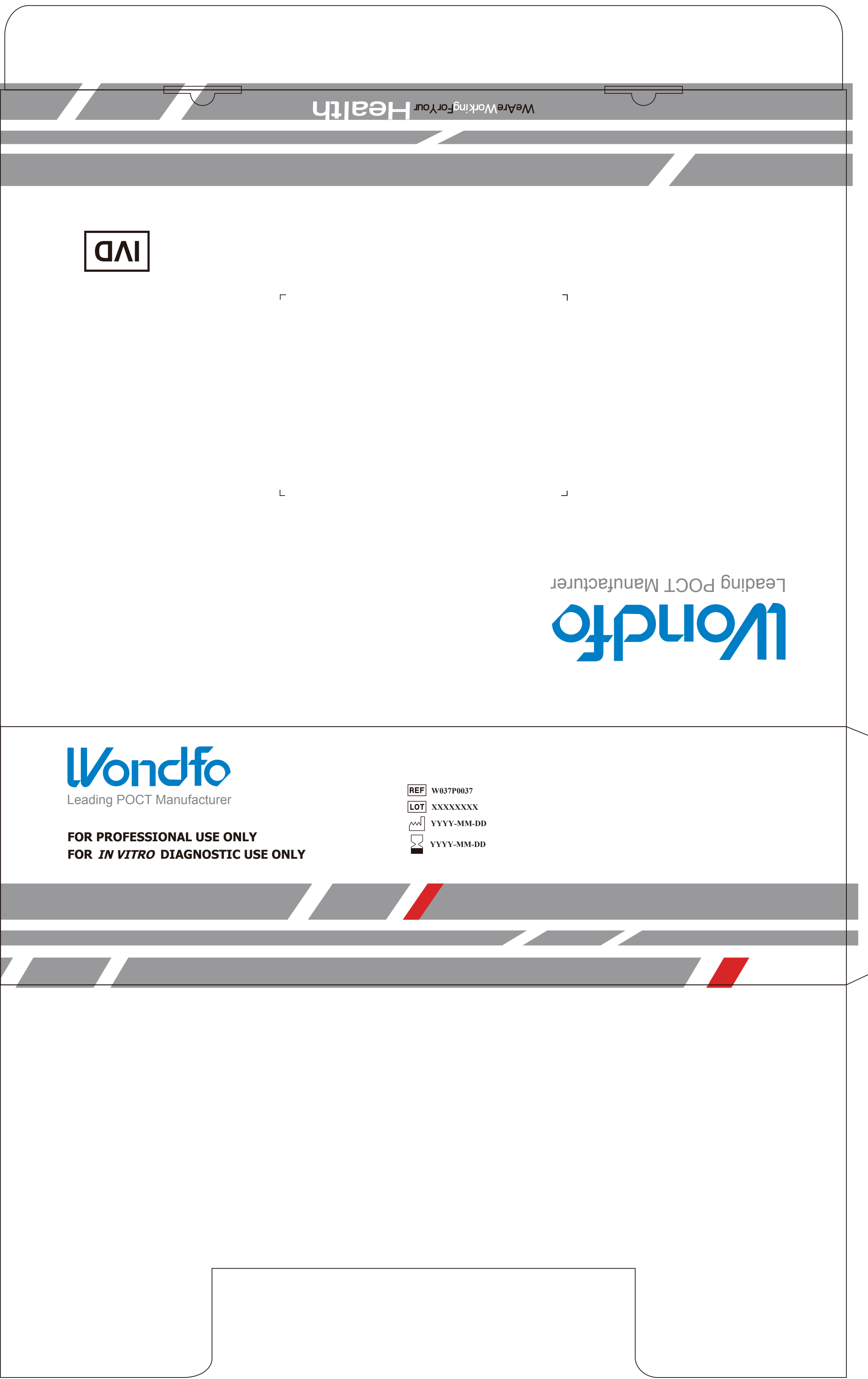
CONTENU :

1. 100 sachets individuels, chacun contenant :
 - Cassette de test
 - Sachet déshydratant
2. 8 Flacons de solution tampon (5 mL/flacon)
3. 1 Notice d'utilisation
4. 100 Tampons alcoolisés
5. 100 Lancettes stériles
6. 100 Coupelles inversées

CONTEÚDO:

1. 100 bolsas individuais, cada uma contendo:
 - Cassete de teste
 - Bolsa dessecante
2. 8 garrafas de buffer (5mL/garrafa)
3. 1 instrução de utilização
4. 100 compressas com álcool
5. 100 lancetas esterilizadas
6. 100 Copos invertidas

Version: A3
Rel.: 2025/06/06



Wondfo
Leading POCT Manufacturer

Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China
Tel: +86-20-32053962 Fax: +86-20-32296063
Website: en.wondfo.com

Wondfo
Leading POCT Manufacturer

Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China
Tel: +86-20-32053962 Fax: +86-20-32296063
Website: en.wondfo.com

距开口 15mm



Wondfo
Leading POCT Manufacturer

Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX
REF W037P0037

YYYY-MM-DD
YYYY-MM-DD

Version: A3

Rel.: 2024/06/25

FOR IN VITRO DIAGNOSTIC USE ONLY

Wondfo

IVD



Guangzhou Wondfo Biotech Co., Ltd.

No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China

Tel: +86-20-32053962 Fax: +86-20-32296063

Website: en.wondfo.com

Sterile Lancet

25
PCS



Rev. A2
Rel.: 2024/12/11



Beijing Ruicheng Medical Supplies Co.,Ltd.
Building 5, No. 8, Yanqi West Road, Yanqi
Economic Development Zone, Huairou District
101407 Beijing P.R. China



Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The
Hague, Netherlands.



0197
STERILE R



Manufactured for Wondfo Biotech by Beijing Ruicheng Medical Supplies Co., Ltd.



Inverted cup



Foshan Yuyang Medical Instrument Co.,Ltd.
Room 501,5th Floor, Building B, No. 1 Kesheng Road,Lishui
Town,Nanhai District, Foshan City,Guangdong, China

LOT



Manufactured for Wondfo Biotech by
Foshan Yuyang Medical Instrument Co.,Ltd.

Language: English
Rev.A3 Ref.20250608



size:38*20mm

**Buffer for Wondfo Malaria
P.f (HRP2/pLDH) Test**

Lot: XXXXXXXX

Ref: W037P0037

Exp: YYYY-MM-DD

Vol:5ml

Store at:1-40°C

Version:A2

Rel.:2024/06/25

size:38*20mm

Wondfo Malaria P.f (HRP2/pLDH) Test



CONTENTS:

1. 10 Individual pouches, each containing:
Test cassette
Desiccant pouch
2. 1 Bottles of buffer(5mL/bottle)
3. 1 Instruction for use
4. 10 Alcohol prep pads
5. 10 Sterile lancets
6. 10 Inverted cups

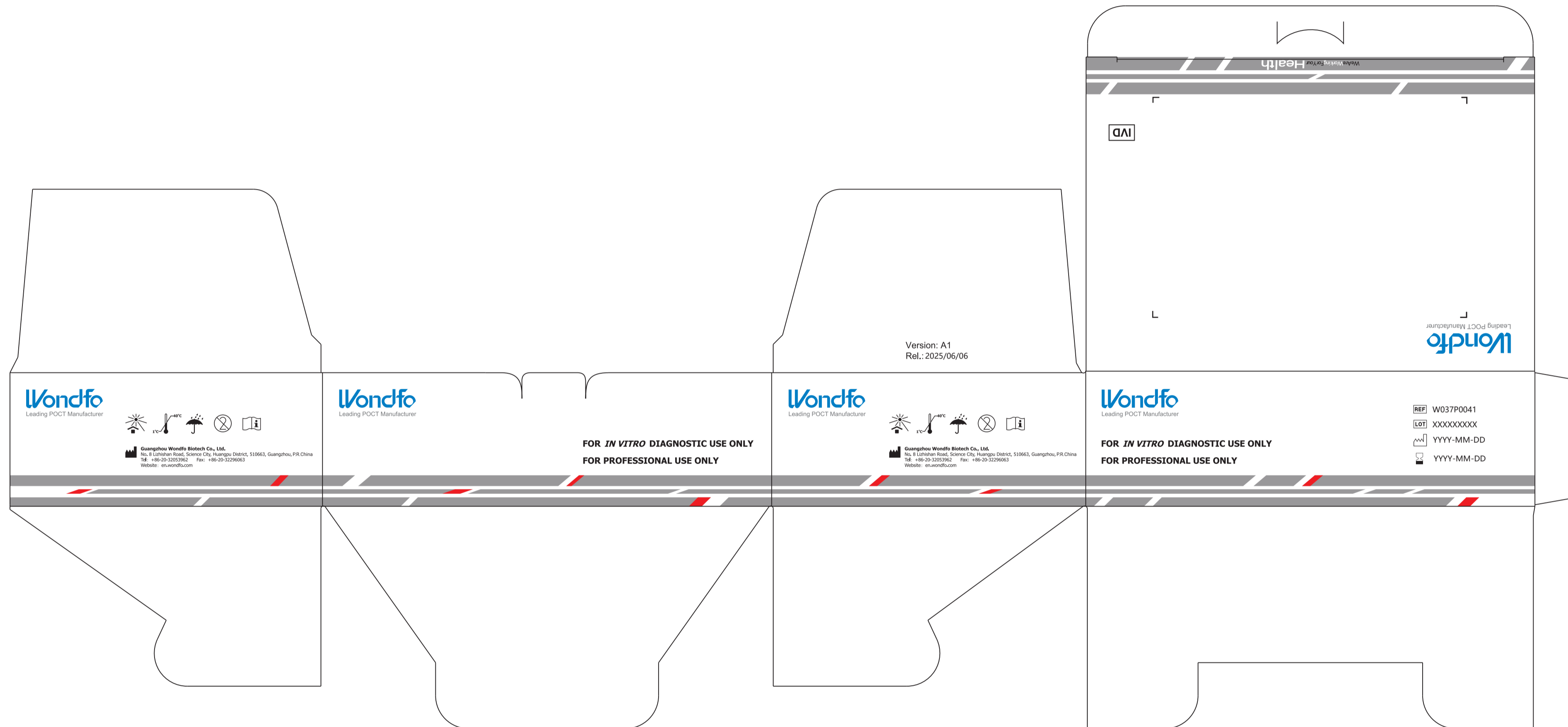
CONTENU :

1. 10 sachets individuels, chacun contenant :
Cassette de test
Sachet déshydratant
2. 1 Flacons de solution tampon (5 mL/flacon)
3. 1 Notice d'utilisation
4. 10 Tampons alcoolisés
5. 10 Lancettes stériles
6. 10 Coupelles inversées

CONTEÚDO:

1. 10 bolsas individuais, cada uma contendo:
Cassete de teste
Bolsa dessecante
2. 1 Garrafas de buffer (5mL/garrafa)
3. 1 Instruções de utilização
4. 10 Compressas com álcool
5. 10 Lancetas esterilizadas
6. 10 Copos invertidos

Version: A1
Rel.: 2025/06/06



距开口 15mm



Wondfo
Leading POCT Manufacturer

Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX

YYYY-MM-DD

REF W037P0041

YYYY-MM-DD

Version: A3

FOR IN VITRO DIAGNOSTIC USE ONLY

Rel.: 2024/06/25

Wondfo

IVD



Guangzhou Wondfo Biotech Co., Ltd.

No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China

Tel: +86-20-32053962 Fax: +86-20-32296063

Website: en.wondfo.com

75mm

10mm

95mm

Sterile Lancet

10
pcs



Rev. A1
Rel.: 2025/06/06



Beijing Ruicheng Medical Supplies Co.,Ltd.
Building 5, No. 8, Yanqi West Road, Yanqi
Economic Development Zone, Hualou
District 101407 Beijing P.R. China



Lotus NL B.V.
Koningin Julianaplein 10, le Verd, 2595AA,
The Hague, Netherlands

LOT



CE

0197


STERILE | R



Manufactured for Wondfo Biotech by Beijing Ruicheng Medical Supplies Co., Ltd.



Inverted cup

 Foshan Yuyang Medical Instrument Co.,Ltd.
Room 501,5th Floor, Building B, No. 1 Kesheng Road,Lishui
Town,Nanhai District, Foshan City,Guangdong, China

LOT



Manufactured for Wondfo Biotech by
Foshan Yuyang Medical Instrument Co.,Ltd.

Language: English
Rev:A1 Ref:2025/09/06



size:38*20mm

**Buffer for Wondfo Malaria
P.f (HRP2/pLDH) Test**

Lot: XXXXXXXX

Ref: W037P0028

Exp: YYYY-MM-DD

Vol:5ml

Store at:1-40°C

Version:A2

Rel.:2024/06/25

size:38*20mm

Instructions for use³

³ English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

Wondfo Malaria P.f (HRP2/pLDH) Test

CATALOG No.

W037P0022	W037P0028	W037P0030
W037P0024	W037P0033	W037P0035
W037P0037	W037P0041	

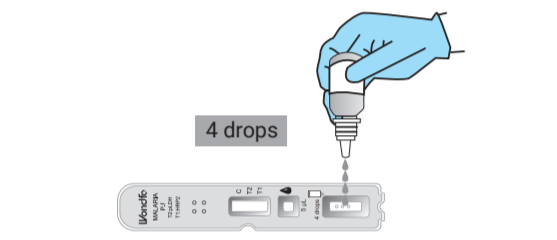
INTENDED USE

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 Pf (HRP2/pLDH) Test should not be used as the sole basis for diagnosis.

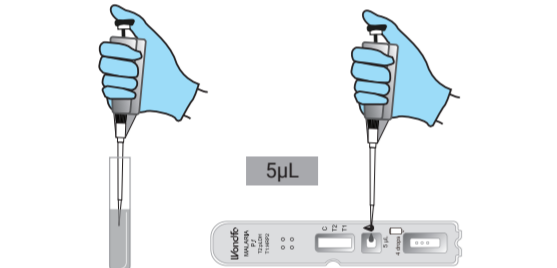
For in vitro diagnostic use only. For professional use only.

BACKGROUND INFORMATION

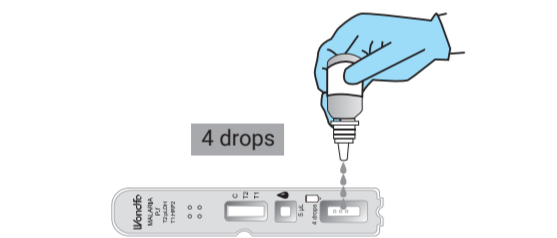
Malaria remains one of the most serious tropical diseases in many regions of the world, mainly occurring in tropical and subtropical areas. Malaria is caused by a parasite that commonly infects the *Anopheles* mosquito which feeds on human blood. There are four kinds of malaria parasites that can infect humans: *P. falciparum*, *P. vivax*, *P. malariae*,



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.



PRINCIPES DE LA PROCÉDURE

Wondfo Malaria P.f (HRP2/pLDH) Test utilise les principes de l'immunochromatographie pour détecter deux cibles : Protéine riche en histidine 2 spécifique au *P. falciparum* (P.f HRP2) et pLDH spécifique au *P. falciparum* (P.f pLDH) dans le sang total humain prélevé au doigt et dans le sang total veineux. Après avoir ajouté l'échantillon dans les puits d'échantillon et la solution tampon dans les puits de tampon, le mélange échantillon-tampon migre vers l'autre extrémité de la cassette par action capillaire. L'antigène présent dans l'échantillon se lie à l'anticorps-or colloïdal pour former le complexe antigène-anticorps-or colloïdal. Le complexe migre ensuite pour capturer l'anticorps spécifique P.f HRP2 / anticorps spécifique P.f pLDH qui est pré-enduit sur la ligne de test de la cassette. Lorsque le niveau d'un antigène cible (P.f HRP2 et/ou P.f pLDH) est égal ou supérieur à la limite de détection (LOD) du test, la ligne de test forme une ligne rouge visible, indiquant un résultat positif. L'IgG lapin-or colloïdal se combine avec l'anticorps polyclonal IgG de chèvre anti-lapin dans la ligne C (ligne de contrôle) pour former une ligne de réaction rouge. La ligne de contrôle est utilisée pour le contrôle de la procédure et montre seulement que la solution tampon a été appliquée avec succès et que les ingrédients actifs des principaux composants de la bande sont fonctionnels.

AVERTISSEMENTS ET PRÉCAUTIONS

- Ce kit est destiné à une utilisation in vitro uniquement.
- Appliquer les précautions standard de biosécurité pour la manipulation et l'élimination du matériel potentiellement infectieux.
- Manipuler tous les échantillons comme étant potentiellement infectieux.
- Porter des gants pour manipuler les échantillons et effectuer le test.
- Éviter les éclaboussures et la formation d'aérosols.
- Nettoyer soigneusement les déversements à l'aide d'un désinfectant approprié.
- Ne pas réutiliser la cassette de test, le coupelle inversée, la lancette et le tampon alcoolisé.
- Ne pas utiliser le kit au-delà de la date de péremption.
- Ne pas utiliser la cassette de test si le sachet est perforé ou mal fermé.
- Ne pas mélanger une solution tampon et une cassette de test provenant de lots différents.
- Ne pas ouvrir le sachet scellé avant d'être prêt à effectuer le test. Une fois ouverte, la cassette de test doit être utilisée dans l'heure qui suit.
- Décontaminer et éliminer tous les échantillons, les kits de réaction et les matériaux potentiellement contaminés en tant que déchets biologiques dangereux.
- Lire entièrement la notice d'utilisation avant d'utiliser le kit. Le non-respect des instructions peut entraîner des résultats inexacts.
- ÉLIMINATION DES DISPOSITIFS DE DIAGNOSTIC : Le dispositif utilisé présente un risque d'infection. Le processus d'élimination des dispositifs de diagnostic doit être conforme aux lois locales sur l'élimination des déchets infectieux ou aux recommandations des laboratoires.
- A tenir hors de portée des enfants.
- La solution tampon contient 2% de Triton X-100, qui ne présente aucun danger pour l'utilisateur si les précautions normales de sécurité en laboratoire sont respectées. Porter des gants de protection. En cas de contact avec la peau et/ou les yeux, rincer immédiatement à l'eau. En cas d'irritation ou de signes de toxicité, consulter un médecin. Respecter la réglementation ou les lois locales pour l'élimination de la solution tampon.

CONTENU DU KIT

Il existe 8 configurations de kits de test. L'inclusion d'un guide rapide, d'une lancette stérile ou d'une lancette sanguine à usage unique est optionnelle/disponible en différentes combinaisons selon la demande de l'utilisateur final.

A. Composants du kit

Chaque sachet scellé individuellement contient une cassette de test et un sachet de dessiccant (uniquement pour le stockage).

Les configurations des composants du kit sont indiquées ci-dessous :

N° de catalogue	W037P0041	W037P0022	W037P0024	W037P0028	W037P0030	W037P0033	W037P0035	W037P0037
Composants	10	25	40	25	25	40	40	100
Cassette (pcs)	10	25	40	25	25	40	40	100
Notice d'utilisation (pcs)	1	1	1	1	1	1	1	1
Solution tampon	1x5mL/bouteille	2x5+0.3 mL/flacon	40x0.3 mL/flacon	2x5 mL/flacon	2x5 mL/flacon	4x5 mL/flacon	4x5 mL/flacon	8x5 mL/flacon
Guide rapide (pcs)	/	25 sachets contenant chacun un guide rapide,	40 sachets contenant chacun un guide rapide,	/	/	/	/	/
Coupelle inversée	10	une coupelle inversée, un tampon alcoolisé et une lancette stérile	une coupelle inversée, un tampon alcoolisé et une lancette stérile	/	/	/	/	/
Tampon alcoolisé (pcs)	10			25	25	40	40	100
Lancette stérile (pcs)	10			25	/	40	/	100
Lancette à aiguille retractable	/	/	/	/	/	25	/	40

INFORMATIONS CONTEXTUELLES

Le paludisme reste l'une des maladies tropicales les plus graves dans de nombreuses régions du monde, principalement dans les zones tropicales et subtropicales. Le paludisme est causé par un parasite qui infecte généralement le moustique anophèle qui se nourrit de sang humain. Il existe quatre types de parasites du paludisme qui peuvent infecter l'homme : *P. falciparum*, *P. vivax*, *P. malariae*, et *P. ovale*. Le paludisme peut également être transmis par des transfusions sanguines, des transplantations d'organes ou le partage d'aiguilles ou de seringues contaminées par le sang d'une personne infectée. Il peut également être transmis de manière congénitale, de la mère à l'enfant à naître. On estime que le paludisme touche plus de 200 millions de personnes dans le monde et cause plus de 400 000 décès chaque année.^{[1],[4]}

WARNINGS AND PRECAUTIONS

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 - 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.
- Do not** reuse the test cassette, inverted cup, lancet, and alcohol prep pad.
- Do not** use the kit beyond the expiration date.
- Do not** use the test cassette if the pouch is punctured or improperly sealed.
- Do not** mix a buffer and a test cassette from different lots.
- Do not** open the sealed pouch until you are ready to conduct the assay. Once opened, use the test cassette within 1 hour.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials as biohazardous waste.
- Read the instructions for use completely before using the kit. Failure to follow directions may yield inaccurate test results.
- 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.
- Keep out of reach of children.
- 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

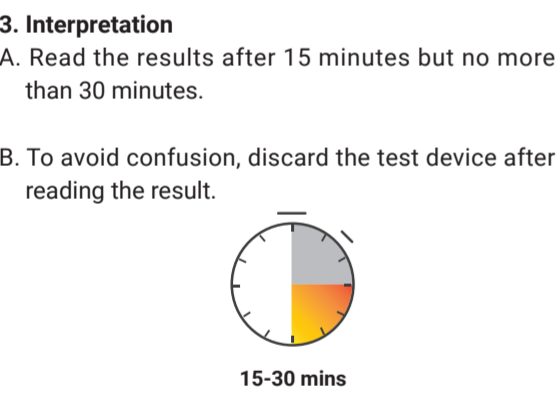
QUALITY CONTROL

- 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.
- 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'		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



PRINCIPES DE LA PROCÉDURE

Wondfo Malaria P.f (HRP2/pLDH) Test utilise les principes de l'immunochromatographie pour détecter deux cibles : Protéine riche en histidine 2 spécifique au *P. falciparum* (P.f HRP2) et pLDH spécifique au *P. falciparum* (P.f pLDH) dans le sang total humain prélevé au doigt et dans le sang total veineux. Après avoir ajouté l'échantillon dans les puits d'échantillon et la solution tampon dans les puits de tampon, le mélange échantillon-tampon migre vers l'autre extrémité de la cassette par action capillaire. L'antigène présent dans l'échantillon se lie à l'anticorps-or colloïdal pour former le complexe antigène-anticorps-or colloïdal. Le complexe migre ensuite pour capturer l'anticorps spécifique P.f HRP2 / anticorps spécifique P.f pLDH qui est pré-enduit sur la ligne de test de la cassette. Lorsque le niveau d'un antigène cible (P.f HRP2 et/ou P.f pLDH) est égal ou supérieur à la limite de détection (LOD) du test, la ligne de test forme une ligne rouge visible, indiquant un résultat positif. L'IgG lapin-or colloïdal se combine avec l'anticorps polyclonal IgG de chèvre anti-lapin dans la ligne C (ligne de contrôle) pour former une ligne de réaction rouge. La ligne de contrôle est utilisée pour le contrôle de la procédure et montre seulement que la solution tampon a été appliquée avec succès et que les ingrédients actifs des principaux composants de la bande sont fonctionnels.

AVERTISSEMENTS ET PRÉCAUTIONS

- Ce kit est destiné à une utilisation in vitro uniquement.
- Appliquer les précautions standard de biosécurité pour la manipulation et l'élimination du matériel potentiellement infectieux.
- Manipuler tous les échantillons comme étant potentiellement infectieux.
- Porter des gants pour manipuler les échantillons et effectuer le test.
- Éviter les éclaboussures et la formation d'aérosols.
- Nettoyer soigneusement les déversements à l'aide d'un désinfectant approprié.
- Ne pas réutiliser la cassette de test, le coupelle inversée, la lancette et le tampon alcoolisé.
- Ne pas utiliser le kit au-delà de la date de péremption.
- Ne pas utiliser la cassette de test si le sachet est perforé ou mal fermé.
- Ne pas mélanger une solution tampon et une cassette de test provenant de lots différents.
- Ne pas ouvrir le sachet scellé avant d'être prêt à effectuer le test. Une fois ouverte, la cassette de test doit être utilisée dans l'heure qui suit.
- Décontaminer et éliminer tous les échantillons, les kits de réaction et les matériaux potentiellement contaminés en tant que déchets biologiques dangereux.
- Lire entièrement la notice d'utilisation avant d'utiliser le kit. Le non-respect des instructions peut entraîner des résultats inexacts.
- ÉLIMINATION DES DISPOSITIFS DE DIAGNOSTIC : Le dispositif utilisé présente un risque d'infection. Le processus d'élimination des dispositifs de diagnostic doit être conforme aux lois locales sur l'élimination des déchets infectieux ou aux recommandations des laboratoires.
- A tenir hors de portée des enfants.
- La solution tampon contient 2% de Triton X-100, qui ne présente aucun danger pour l'utilisateur si les précautions normales de sécurité en laboratoire sont respectées. Porter des gants de protection. En cas de contact avec la peau et/ou les yeux, rincer immédiatement à l'eau. En cas d'irritation ou de signes de toxicité, consulter un médecin. Respecter la réglementation ou les lois locales pour l'élimination de la solution tampon.

CONTENU DU KIT

Il existe 8 configurations de kits de test. L'inclusion d'un guide rapide, d'une lancette stérile ou d'une lancette sanguine à usage unique est optionnelle/disponible en différentes combinaisons selon la demande de l'utilisateur final.

A. Composants du kit

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Les configurations des composants du kit sont indiquées ci-dessous :

N° de catalogue	W037P0041	W037P0022	W037P0024	W037P0028	W037P0030	W037P0033	W037P0035	W037P0037
Composants	10	25	40	25	25	40	40	100
Cassette (pcs)	10	25	40	25	25	40	40	100
Notice d'utilisation (pcs)	1	1	1	1	1	1	1	1
Solution tampon	1x5mL/bouteille	2x5+0.3 mL/flacon	40x0.3 mL/flacon	2x5 mL/flacon	2x5 mL/flacon	4x5 mL/flacon	4x5 mL/flacon	8x5 mL/flacon
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Lancette à aiguille retractable	/	/	/	/	/	25	/	40

INFORMATIONS CONTEXTUELLES

Le paludisme reste l'une des maladies tropicales les plus graves dans de nombreuses régions du monde, principalement dans les zones tropicales et subtropicales. Le paludisme est causé par un parasite qui infecte généralement le moustique anophèle qui se nourrit de sang humain. Il existe quatre types de parasites du paludisme qui peuvent infecter l'homme : *P. falciparum*, *P. vivax*, *P. malariae*, et *P. ovale*. Le paludisme peut également être transmis par des transfusions sanguines, des transplantations d'organes ou le partage d'aiguilles ou de seringues contaminées par le sang d'une personne infectée. Il peut également être transmis de manière congénitale, de la mère à l'enfant à naître. On estime que le paludisme touche plus de 200 millions de personnes dans le monde et cause plus de 400 000 décès chaque année.^{[1],[4]}

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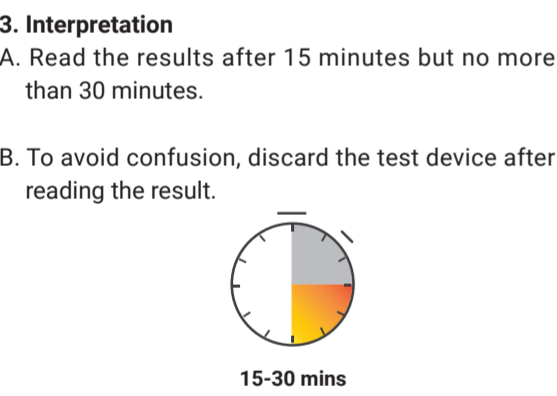
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Lancette à aiguille retractable	/	/	/	/	/	25	/	40

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- Keep out of reach of children.
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QUALITY CONTROL

CONTRÔLE DE QUALITÉ

- Contrôle interno : Ce kit contém uma função de controle integrada em tant que controle de procedimento, a região de controle (C). Uma linha colorida se desenvolve na região de controle (C) após o acréscimo de 10 µL de amostra e a formação de uma linha colorida na região de teste (T). Se a linha de teste não se desenvolver na região de teste (T), o teste é inválido. Verifique a procedimento e repita o teste com um novo dispositivo.
- Controle externo : O kit de teste não fornece controle externo.

INTERPRETAÇÃO DOS RESULTADOS

Linhas que l'on voit	Figure	Lecture et interprétation des résultats
----------------------	--------	---

			Resultado : Invalide. Ação : Pegue uma nova casete e repita o teste. Verifique o fabricante local ou o fabricante si des resultados inválidos contínuo d'appareil.
Aucune ligne à « C » (contrôle)			
			

		Resultado : Négatif. Ação : Non
Présence de la ligne à « C » et d'aucune autre ligne		

Lignes que l'on voit	Figure	Lecture et interprétation des résultats
----------------------	--------	---

		Resultado : Positif. 1. Les lignes à « C », « T1 » et « T2 » indiquent un résultat positif pour P. f HRP2 et P. f pLDH. 2. La ligne à « C » et « T1 » indique un résultat positif pour Pf HRP2. 3. La ligne à « C » et « T2 » indique un résultat positif pour Pf pLDH.
Présence de la ligne à « C » et à « T1 » et/ou « T2 ».		

		Resultado : Négatif. Ação : Non
Présence de la ligne à « C » et à « T1 » et/ou « T2 ».		

NOTAS

Português

Wondfo Wondfo Malaria P.f (HRP2/pLDH) Test

CATÁLOGO Nº.			
W037P0022	W037P0028	W037P0030	
W037P0024	W037P0033	W037P0035	
W037P0037	W037P0041		

USO PRETENDIDO

O Wondfo Malaria Pf (HRP2/pLDH) Test é um ensaio imunocromatográfico de diagnóstico rápido destinado à detecção qualitativa da proteína-2 rica em histidina específica do P. falciparum (Pf HRP2) e da pLDH específica do P. falciparum (Pf pLDH) no sangue total humano obtido por punção no dedo e no sangue total venoso. É destinado a ser utilizado por profissionais de laboratório e em centros de saúde por profissionais de saúde ou prestadores de cuidados não especializados com formação adequada. É utilizado como auxiliar no diagnóstico da infecção por P. falciparum em doentes sintomáticos, incluindo testes pediátricos. Os resultados do Wondfo Malaria Pf (HRP2/pLDH) Test não devem ser utilizados como única base para o diagnóstico.

Apenas para diagnóstico in vitro. Apenas para uso por profissionais.

INFORMAÇÕES GERAIS

A malária continua a ser uma das doenças tropicais mais graves em muitas regiões do mundo, ocorrendo principalmente em áreas tropicais e subtropicais. A malária é causada por um parasita que geralmente infecta o mosquito Anopheles, que se alimenta de sangue humano. Existem quatro tipos de parasitas da malária que podem infectar os seres humanos: P. falciparum, P. vivax, P. malariae e P. ovale. A malária também pode ser transmitida por transfusões de sangue, transplante de órgãos ou partilha de agulhas/seringas contaminadas com sangue de uma pessoa infectada. Também pode ser transmitida congenitamente da mãe para o feto. Estima-se que afete mais de 200 milhões de pessoas em todo o mundo e cause mais de 400.000 mortes por ano ^[14].

CONTEÚDO DO KIT

CONTEÚDO DO KIT

- Controlo interno: Este kit contém uma função de controlo integrada com controlo processual, a região de controlo (C). Uma linha colorida desenvolve-se na região de controlo (C) após a adição da amostra e do buffer. Se não se desenvolver uma linha colorida na região C, o teste é inválido. Verifique o procedimento e repita o teste com um novo dispositivo.
- Controlo externo: O kit de teste não fornece controlo externo.

INTERPRETAÇÃO DOS RESULTADOS

Linhas que vê	Imagem	Leitura e interpretação dos resultados
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		Resultado : Invalído. Ação: Pegue uma nova casete e repita o teste. Por favor, contacte o distribuidor ou fabricante local se continuarem a aparecer resultados inválidos.
Sem linha/sem "C" (controlo)		
		

		Resultado : negativo. Ação: Não
Linha em "C" e nenhuma outra linha		

Linhas que vê	Imagem	Leitura e interpretação dos resultados
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		Resultado : Positivo. 1. A linha em "C", "T1" e "T2" indica positivo para P. f HRP2 e P. f pLDH. 2. A linha em "C" e "T1" indica positivo para Pf HRP2. 3. A linha em "C" e "T2" indica positivo para Pf pLDH.
Linha em "C" e em "T1" e/ou "T2"		

		Resultado : Négatif. Ação: Non
Linha em "C" e em "T1" e/ou "T2"		

Note : Veuillez contacter le distributeur local ou le fabricant si vous soupçonnez une augmentation du taux de résultats faussement négatifs ou positifs.

LIMITAÇÕES DE LA PROCÉDURE

- O kit é um teste qualitativo concebido para detectar os antígenos de proteína rica em histidina 2 específica ao P. falciparum (P. f HRP2) e pLDH específica ao P. falciparum (P. f pLDH) no sangue total humano unicamente.
- Lors du test, suivre scrupuleusement la notice d'utilisation. Toute erreur de manipulation entrainera un résultat erroné.
- Utiliser l'EDTA, l'héparine sodique et le citrate de sodium comme anticoagulants. Ne pas utiliser d'autres anticoagulants.
- Des résultats faussement négatifs peuvent se produire dans les cas suivants :
 - Très faibles concentrations d'antigènes/densités de parasites, par exemple < 100 parasites/µl. Il convient de noter que la plupart des cas cliniques présentent des densités parasitaires très élevées.
 - Densités parasitaires très élevées (très exceptionnelles, effet prozone ou effet de crochets élevés) pour l'antigène HRP2.
 - Les délétions du gène HRP2 n'entraînent aucune production de l'antigène HRP2, ce qui est particulièrement important pour les mRDT qui détectent cet antigène. Ces délétions ont été identifiées pour la première fois en Amazonie péruvienne, mais ont depuis été signalées dans diverses régions du monde où le paludisme est endémique.
- *Fraction évacuée de liquide interstitiel due à la traite de l'extrémité du doigt.

- La présence de la ligne de contrôle signifie seulement qu'il y a eu migration du liquide ajouté. Elle ne garantit pas que :
 - Le bon échantillon a été utilisé.
 - L'échantillon a été appliqué correctement.
 - L'échantillon et le kit ont été correctement conservés.
 - La procédure de test a été suivie correctement.

- Comme pour tous les tests de diagnostic, un diagnostic clinique définitif ne doit pas être basé sur le résultat d'un seul test, mais doit être déterminé par un professionnel de la santé en conjonction avec les résultats cliniques et les résultats d'autres tests et évaluations de laboratoire. Les résultats du Test Wondfo Malaria Pf (HRP2/pLDH) Test ne doivent pas être utilisés comme seule base de diagnostic.

- Le produit peut donner un résultat faussement positif au Pf même si le patient a été traité contre le paludisme plusieurs semaines avant le test. Le test ne peut pas être utilisé pour surveiller la réponse au traitement antipaludique.

CARACTÉRISTIQUES DE PERFORMANCE^[2]

Étude de performance clinique

Lieu d'évaluation	SD Bioline	Wondfo Malaria Pf (HRP2/pLDH) Test		
		Positif	Négatif	Total

Labo-ratoire Wondfo	<i>Positif au Pf</i>	102	0	102	Sensibilité : 100,00% (96,37-100,00%)
	<i>Négatif au Pf</i>	1	625	626	Spécificité : 99,84% (99,10-99,97%)

* Type d'échantillon utilisé pour SD Bioline et Wondfo : sang total veineux.

- Évaluation externe
- 2.1 Sensibilité et spécificité du diagnostic

Lieu d'évaluation	SD Bioline	Wondfo Malaria Pf (HRP2/pLDH) Test		
		Positif	Négatif	Total

* Type d'échantillon utilisé pour SD Bioline : sang total veineux ; Type d'échantillon utilisé pour Wondfo : sang total prélevé au doigt.

2.2 Comparaison avec le test PCR

Lieu d'évaluation	PCR	Wondfo Malaria Pf (HRP2/pLDH) Test		
		Positif	Négatif	Total

* Type d'échantillon utilisé pour la PCR : sang total veineux ; Type d'échantillon utilisé pour Wondfo : sang total prélevé au doigt.

NOTAS

Português

PRINCÍPIOS DO PROCEDIMENTO

O Wondfo Malaria P.f (HRP2/pLDH) Test utiliza os princípios da imunocromatografia para detectar dois antígenos: proteína-2 rica em histidina específica do P. falciparum (P. f HRP2) e pLDH específica do P. falciparum (P. f pLDH) no sangue total humano obtido por punção no dedo e no sangue total venoso.

Após adicionar a amostra à cavidade de amostra e adicionar o buffer à cavidade deste, a mistura de amostra e buffer migra para a outra extremidade da casete por ação capilar. O antígeno na amostra irá ligar-se ao anticorpo-colóide dourado para formar o complexo antígeno-anticorpo-colóide dourado. O complexo migra ainda mais para capturar o anticorpo específico Pf HRP2 / anticorpo específico Pf pLDH que está pré-revestido na linha de teste da casete. Quando o nível do antígeno alvo (Pf HRP2 e/ou Pf pLDH) é igual ou superior ao limite de detectabilidade (LoD) do ensaio, a linha de teste forma uma linha vermelha visível, indicando um resultado positivo. O colóide IgG-ouro de coelho combina-se com o anticorpo policlonal IgG anti-coelho de cabra na linha C (linha de controlo) para formar uma linha de reacção vermelha. A linha de controlo é utilizada para controlo processual e mostra apenas que o buffer foi aplicado com sucesso e que os ingredientes activos dos componentes principais na tira estão funcionais.

CONTEÚDO DO KIT

Existem 8 configurações dos kits de teste. A inclusão de um guia rápido, lanceta esterilizada ou lanceta para sangue de uso único é opcional/disponível em diferentes combinações, conforme a solicitação do utilizador final. A Componentes do kit Cada embalagem selada individualmente contém uma casete de teste e uma bolsa dessecante (apenas para fins de armazenamento). As configurações dos componentes do kit estão indicadas abaixo:

Catálogo nº	W037P0041	W037P0022	W037P0024	W037P0028	W037P0030	W037P0033	W037P0035	W037P0037
Cassete (unidades)	10	25	40	25	25	40	40	100
Instruções (unidades)	1	1	1	1	1	1	1	1
Buffer	1x5mL/garrafa	25 × 0,3 mL/frasco	40 × 0,3 mL/frasco	2x5mL/garrafa	2x5mL/garrafa	4x5 mL/garrafa	4x5 mL/garrafa	5 mL/garrafa
Guia rápido (unidades)	/	25 bolsas, cada uma contendo um guia rápido, uma copo invertido, uma compressa com álcool e uma lanceta esterilizada.	40 bolsas, cada uma contendo um guia rápido, uma copo invertido, uma compressa com álcool e uma lanceta esterilizada.	/	/	/	/	/
Copo invertido (unidades)	10	/	/	25	25	40	40	100
Compressa com álcool (unidades)	10	/	/	25	25	40	40	100
Lanceta esterilizada (unidades)	10	/	/	25	/	40	/	100
Lanceta descartável (unidades)	/	/	/	/	25	/	40	/

CONTEÚDO DO KIT

Existem 8 configurações dos kits de teste. A inclusão de um guia rápido, lanceta esterilizada ou lanceta para sangue de uso único é opcional/disponível em diferentes combinações, conforme a solicitação do utilizador final. A Componentes do kit Cada embalagem selada individualmente contém uma casete de teste e uma bolsa dessecante (apenas para fins de armazenamento). As configurações dos componentes do kit estão indicadas abaixo:

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Copo invertido (unidades)	10	/	/	25	25	40	40	100
Compressa com álcool (unidades)	10	/	/	25	25	40	40	100
Lanceta esterilizada (unidades)	10	/	/	25	/	40	/	100
Lanceta descartável (unidades)	/	/	/	/	25	/	40	/

CARACTERÍSTICAS DE DESEMPENHO^[2]

Estudo de desempenho clínico

Lieu d'avalaição	Linha SD Bioline	Wondfo Malaria Pf (HRP2/pLDH) Test		
		Positivo	Negativo	Total

Labo-ratório Wondfo	<i>Pf Positivo</i>	102	0	102	Sensibilidade : 100,00% (97,84-100,00%)
	<i>Pf Negativo</i>	1	625	626	Especificidade : 99,84% (99,10-99,97%)

* Tipo de amostra utilizada para SD Bioline e Wondfo: sangue total venoso.

- Avaliação externa
- 2.1 Sensibilidade e especificidade do diagnóstico

Local da avaliação	Linha SD Bioline	Wondfo Malaria Pf (HRP2/pLDH) Test		
		Positivo	Negativo	Total

* Tipo de amostra utilizada para SD Bioline : sangue total venoso ; Tipo de amostra utilizado para o Wondfo : sangue total por punção no dedo.

2.2 Comparação com o ensaio PCR

Local da avaliação	PCR	Wondfo Malaria Pf (HRP2/pLDH) Test		
		Positivo	Negativo	Total

* Tipo de amostra utilizado para PCR : sangue total venoso ; Tipo de amostra utilizado para Wondfo : sangue total por punção no dedo.

2.3 Comparison among different specimen types

Lieu d'évaluation	Wondfo Malaria Pf (HRP2/pLDH) Test	SD Bioline Sang total veineux	Positif		Négatif		Résultat du test (IC 95 %)
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* Type d'échantillon utilisé pour SD Bioline : sang total veineux ; Type d'échantillon utilisé pour Wondfo : sang total veineux et sang total prélevé au doigt.

Étude de performance de l'analyse

- La répétabilité et la reproductibilité de Wondfo Malaria Pf (HRP2/pLDH) Test ont été démontrées par un panel interne conformément à la norme CLSI EP-05 (A3). Une reproductibilité de 100 % a été observée dans les études à l'intérieur des séries, entre les séries, entre les lots, ainsi qu'entre les sites et les opérateurs.

- Les substances interférentes potentielles suivantes n'ont pas d'impact sur le Test Wondfo Malaria Pf (HRP2/pLDH) Test

No.	Type	Substances interférentes
1		HAMA
2		Receveurs de transfusions sanguines multiples
3		Anticorps anti-dsDNA
4		Anticorps anti-cardiolipine IgG
5		Anticorps anti-cardiolipine IgM
6		Facteurs rhumatoïdes
7		IgG
8		IgM
9	Endogène	Albumine
10		Bilirubine totale
11		Triglycérides
12		Gonadotrophine chorionique humaine
13		Cholestérol
14		Lipoprotéines de faible densité
15		Hémoglobine
16		Bilirubine directe
17		Chloroquine Phosphate
18		Artemisinin
19		Amoxicillin
20		Cefalexin
21		Doxycycline Hyclate
22		Erythromycin
23	Exogéno	Ibuprofen

NOTAS

Português

PRINCÍPIOS DO PROCEDIMENTO

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Copo invertido (unidades)	10	/	/	25	25	40	40	100
Compressa com álcool (unidades)	10	/	/	25	25	40	40	100
Lanceta esterilizada (unidades)	10	/	/	25	/	40	/	100
Lanceta descartável (unidades)	/	/	/	/	25	/	40	/

CONTEÚDO DO KIT

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Instruções (unidades)	1	1	1	1	1	1	1	1
Buffer	1x5mL/garrafa	25 × 0,3 mL/frasco	40 × 0,3 mL/frasco	2x5mL/garrafa	2x5mL/garrafa	4x5 mL/garrafa	4x5 mL/garrafa	5 mL/garrafa

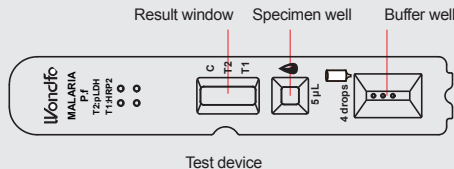
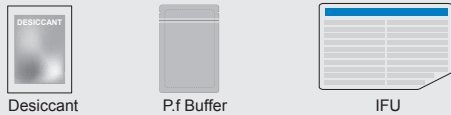
Quick User Guide

QUICK GUIDE

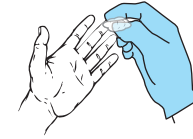
For fingerstick whole blood

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.

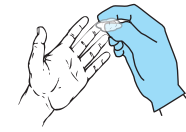
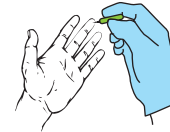
Material provided



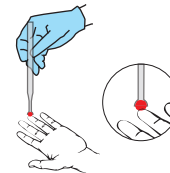
- 1 Wash hands and put on protective gloves before testing. Wipe the fingertip to be lanced with an alcohol prep pad. Select the middle or ring finger for sampling and avoid calloused areas of the finger.



- 2 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.

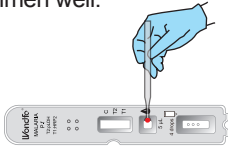


- 3 Dip the circular end of the inverted cup into the blood specimen (5µL).



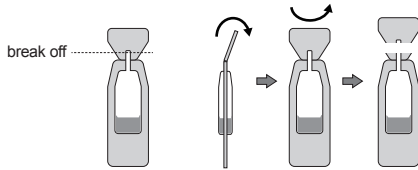
! Fingerstick whole blood should be tested immediately.

4 Place the circular end of the inverted cup into the specimen well.

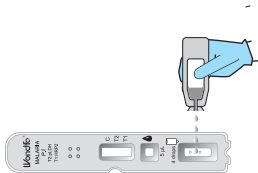


! Do not add into buffer well.

5 Break off the head of buffer along with the crease line and then twist it off.



6 Add 4 drops of buffer into the buffer well vertically and start timing.



! Do not add buffer into the specimen well.

7 Read the results after 15 minutes but no more than 30 minutes. To avoid confusion, discard the test device after reading the result.



15-30 mins

! Do not wait more than 30 minutes to read the result.

HOW TO INTERPRET THE TEST

Lines that you see	Picture	Read and Interpretation of Results
No line at 'C' (control)		<p>Result: Invalid.</p> <p>Action: Take a new cassette and repeat the test. Please contact the local distributor or manufacturer if invalid results continuously appear.</p>
Line at 'C' and No other line		<p>Result: Negative.</p> <p>Action: No</p>
Line at 'C' and at 'T1' and/or 'T2'		<p>Result: Positive.</p> <ol style="list-style-type: none"> Line at 'C', 'T1' and 'T2' indicates positive for P.f HRP2 and P.f pLDH. Line at 'C' and 'T1' indicates positive for P.f HRP2. Line at 'C' and 'T2' indicates positive for P.f pLDH. <p>Note: Line intensity may vary from faint to strong intensity. Consider a faint test line as a positive result.</p> <p>Action: No</p>

DISPOSE

! IMPORTANT

Put all used disposable components into the medical waste container. Dispose according to local infectious waste disposal laws and regulations.

