

## WHO Prequalification of In Vitro Diagnostics PUBLIC 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 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

#### 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.”*

#### Assay description

According to the claim of assay description from Guangzhou Wondfo Biotech Co., Ltd, “*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."*

### Test kit contents

Component	25 Tests(T) (W037P0022)	40 T (W037P0024)	25 T (W037P0028)	25 T (W037P0030)	40 T (W037P0033)	40 T (W037P0035)	100 T (W037P0037)
Cassette (pieces (pcs))	25	40	25	25	40	40	100
Instructions	1	1	1	1	1	1	1
Buffer	25×0.3 mL/vial	40×0.3 mL/vial	2×5 mL/bottle	2×5 mL/bottle	4×5 mL/bottle	4×5 mL/bottle	8×5 mL/bottle
Quick guide (pcs)	25 pouches, each containing one quick guide:	40 pouches, each containing one quick guide:	/	/	/	/	/
Inverted cup (pcs)	one	one	25	25	40	40	100
Alcohol prep pad (pcs)	one	one	25	25	40	40	100
Sterile lancet (pcs)	one inverted cup, one alcohol prep pad, one sterile lancet.	one inverted cup, one alcohol prep pad, 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 should be stored at 1-40 °C.

**Shelf-life upon manufacture**

24 months.

**Warnings/limitations**

Refer to the current version of the manufacturer's instructions for use attached to this public 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 nonHRP2 expressing specimens in areas with high prevalence of *pfhrp2/3* gene deletions<sup>1</sup>. This test does not meet these criteria and is not recommended for use in such settings.

**Prioritization for Prequalification Assessment**

Based on the established eligibility criteria, Wondfo Malaria P.f (HRP2/pLDH) Test was given priority for WHO prequalification assessment.

**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.

**Commitment for prequalification**

The manufacturer will provide additional information regarding accuracy of measurement and additional details regarding the analytical specificity study report.

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.

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

## Manufacturing site inspection

At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current assessment performed at a manufacturing site for in vitro diagnostic products and summarises the assessment findings.

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

All published WHOPIRs are with the agreement of the manufacturer.

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 (Guangzhou Wondfo Biotech Co., Ltd.) 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 <sup>#</sup> 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/ $\mu$ L	
Invalid rate % (N= 1322)	0/1322, 0.0 %	
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 <sup>st</sup> 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 $\mu$ L 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 meets the WHO prequalification requirements.

## **Labelling**

- 1. Labels**
- 2. Instructions for use**

## **1. Labels**

### **1.1 Labels and packaging artwork for 25 Tests(T) (W037P0022)**

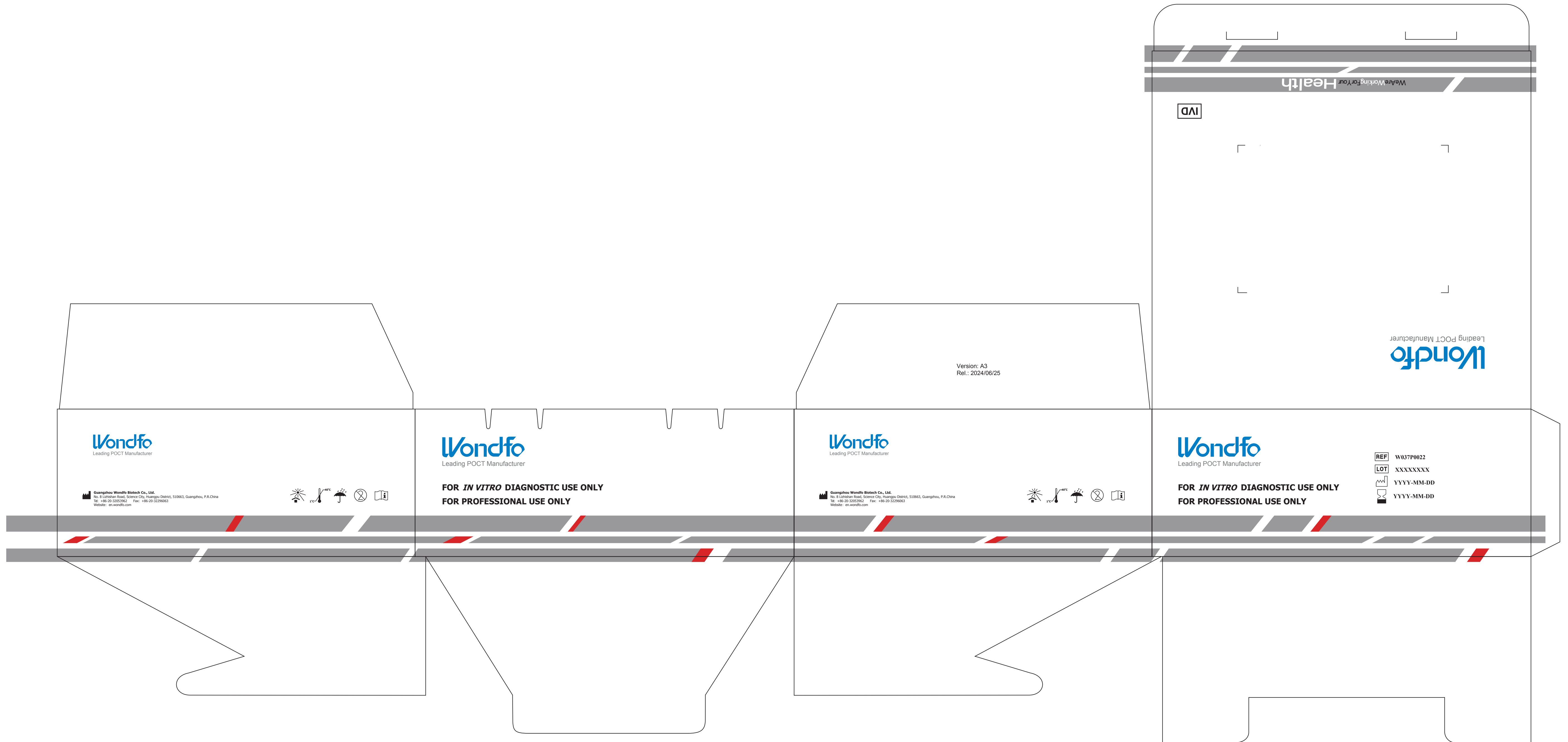
# Wondfo Malaria P.f (HRP2/pLDH) Test



## 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

Version: A2  
Rel.: 2024/06/25



距开口15mm



Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX  
REF W037P0022

YYYY-MM-DD  
YYYY-MM-DD

Version: A3  
Rel.: 2024/06/25

FOR IN VITRO DIAGNOSTIC USE ONLY



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

10mm

Wondfo



Accessories pouch

CONTENT:

- 1 Quick guide
- 1 Inverted cup
- 1 Alcohol prep pad
- 1 Sterile lancet



Rev.A2  
Rel.:2024/06/25

14.798mm

13mm

100mm

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

REF W037P0022

YYYY-MM-DD

YYYY-MM-DD

1°C

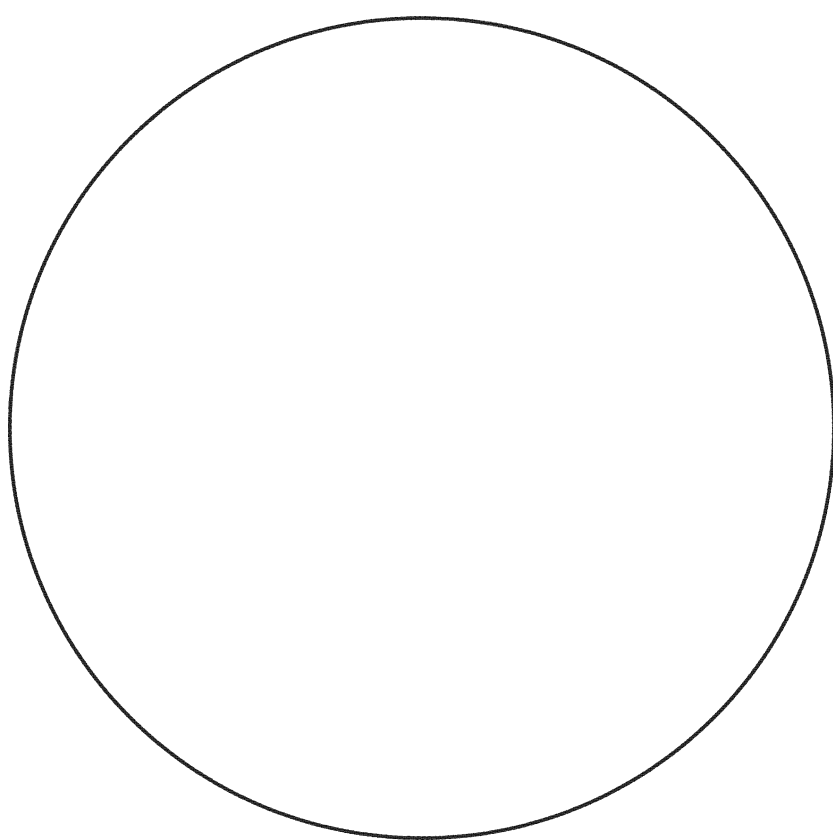
40°C









Rev.A2  
Rel.:2024/06/25

三边封；供应商预留开口

封边  
10mm





	<div><div></div><div>ART NO.: C/NO.: QTY: PCS N.W: KGS G.W: KGS MEAS: 55.7×52.7×44.2 CM</div></div>		<div><div></div><div>ART NO.: C/NO.: QTY: PCS N.W: KGS G.W: KGS MEAS: 55.7×52.7×44.2 CM</div></div>

## **1.2 Labels and packaging artwork for 40 T (W037P0024)**

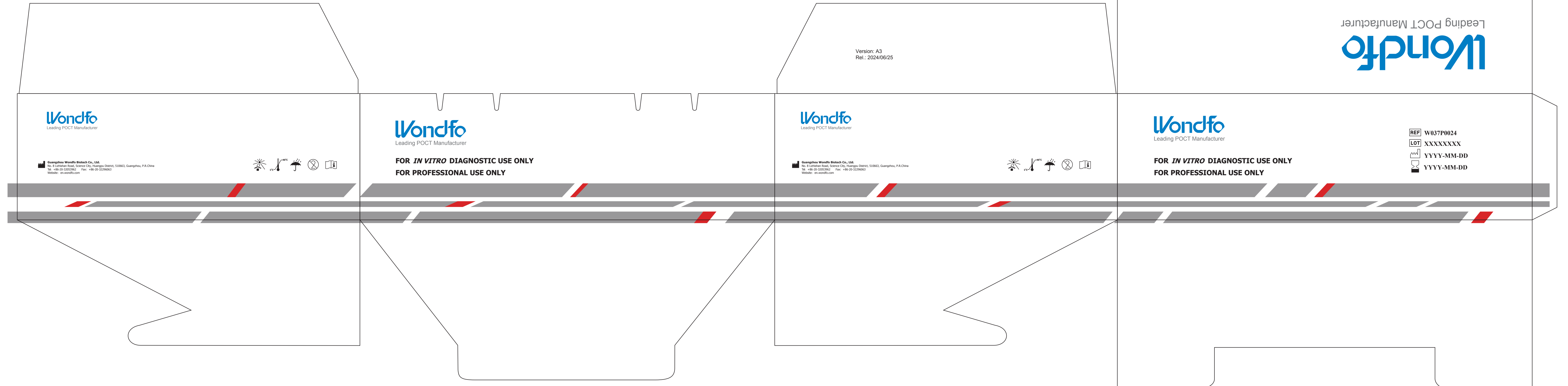
# Wondfo Malaria P.f (HRP2/pLDH) Test




## 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

Version: A2  
Rel.:2024/06/25



距开口15mm



Leading POCT Manufacturer

▽  
Σ  
1

Wondfo Malaria P.f (HRP2/pLDH) Test

LOT

XXXXXXXX

REF

W037P0024

⌚

YYYY-MM-DD


📶

YYYY-MM-DD

Version: A3

Rel.: 2024/06/25

FOR IN VITRO DIAGNOSTIC USE ONLY



IVD

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Guangzhou Wondfo Biotech Co., Ltd.

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Website: en.wondfo.com

10mm

**Wondfo**



## Accessories pouch

### CONTENT:

- 1 Quick guide
- 1 Inverted cup
- 1 Alcohol prep pad
- 1 Sterile lancet



Rev.A2  
Rel.:2024/06/25

14.798mm

13mm

100mm

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

REF

W037P0024

YYYY-MM-DD

YYYY-MM-DD

1°C

40°C

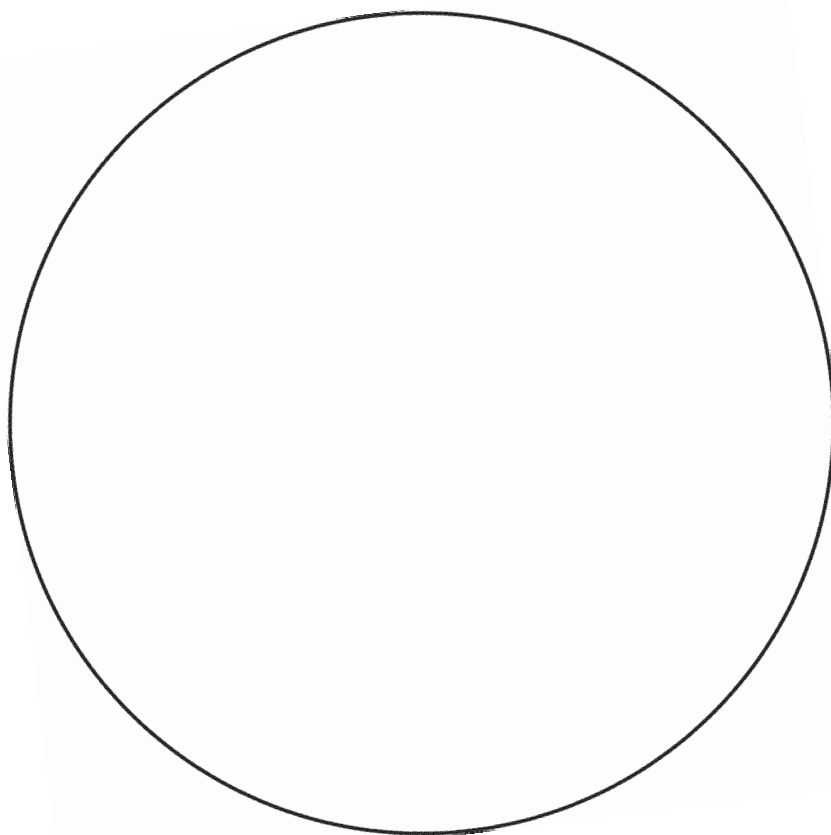
Rev.A2

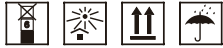
Rel.:2024/06/25

三边封；供应商预留开口

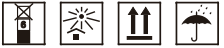
封边  
10mm







ART NO.:  
C/NO.:  
QTY: PCS  
N.W: KGS  
G.W: KGS  
MEAS: 58.7×47.7×40.2 CM



ART NO.:  
C/NO.:  
QTY: PCS  
N.W: KGS  
G.W: KGS  
MEAS: 58.7×47.7×40.2 CM

### **1.3 Labels and packaging artwork for 25 T (W037P0028)**

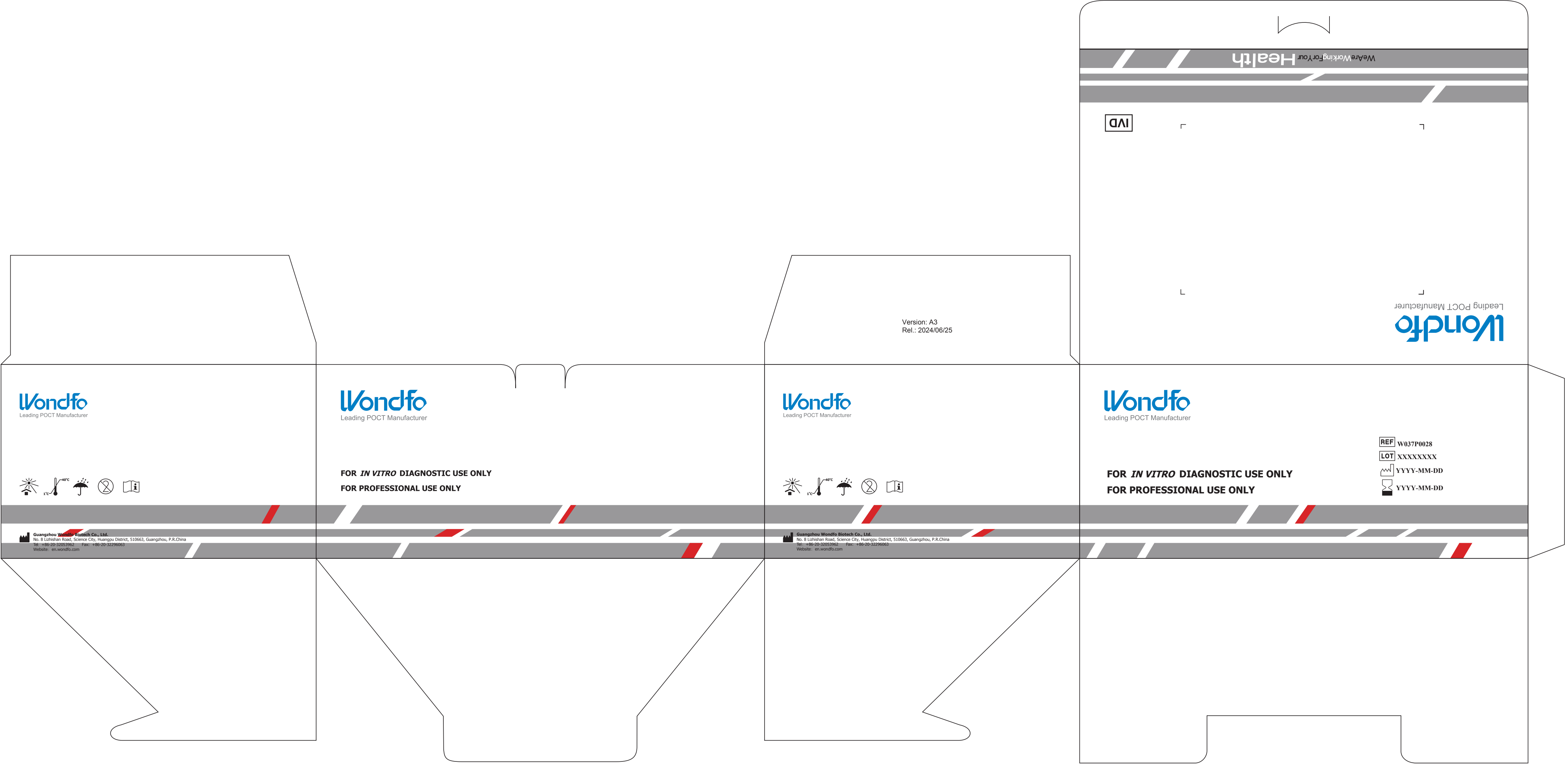
# Wondfo Malaria P.f (HRP2/pLDH) Test



## 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

Version: A2  
Rel.: 2024/06/25



距开口15mm



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

LOT XXXXXXXX  
REF W037P0028

YYYY-MM-DD  
YYYY-MM-DD

Version: A3  
Rel.: 2024/06/25

FOR IN VITRO DIAGNOSTIC USE ONLY

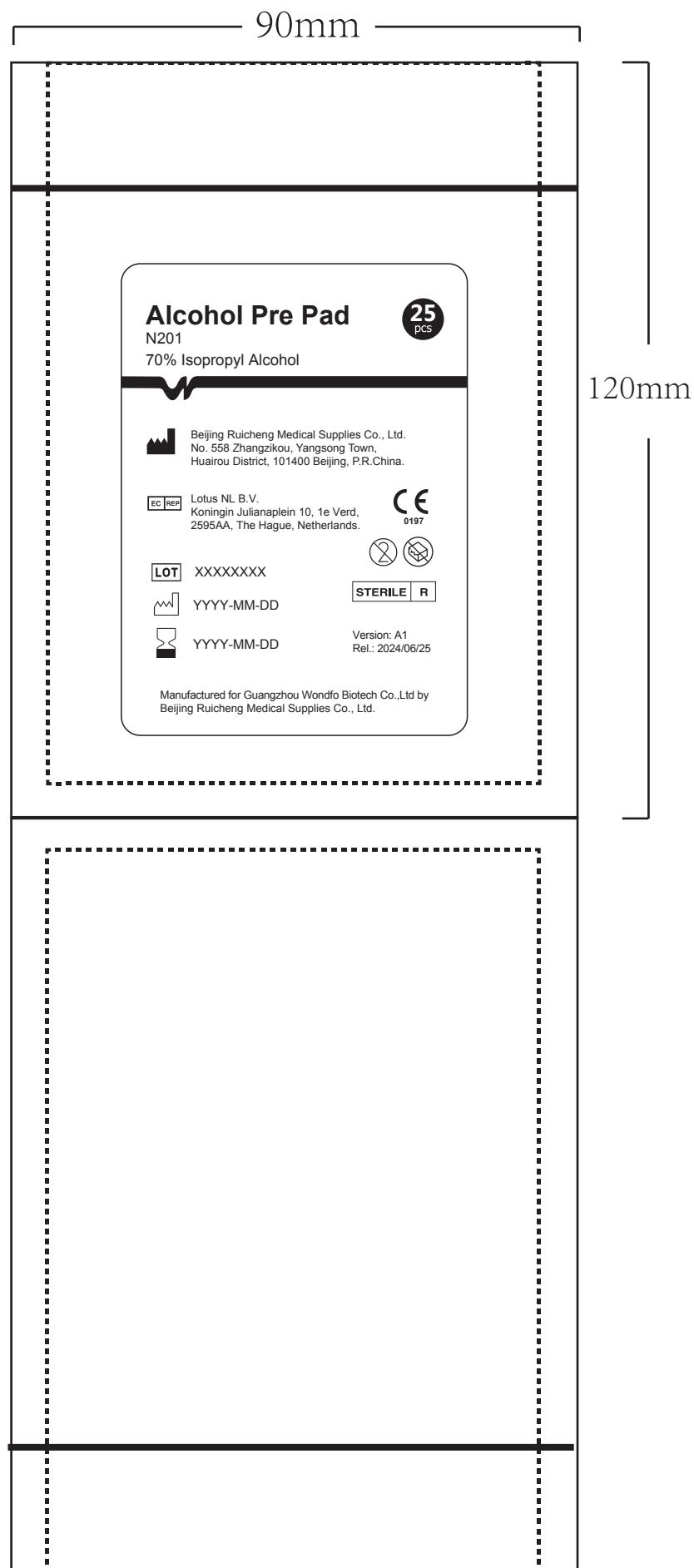


**Guangzhou Wondfo Biotech Co., Ltd.**  
No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China  
Tel: +86-20-32053962 Fax: +86-20-32296063  
Website: en.wondfo.com

封口

成品：105x75mm图案：54x65mm







## Inverted cup



Foshan Nanhai Yuyang Plastic Mould Co., Ltd.  
No. 26, Honggang Industrial Zone, Lishui Town,  
Nanhai District, Foshan City

LOT

XXXXXXXX



YYYY-MM-DD



YYYY-MM-DD



Manufactured for Wondfo Biotech by  
Foshan Nanhai Yuyang Plastic Mould Co., Ltd.

Language: English  
Rev A01 Rel. 20201118



size:38\*20mm

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

Lot: XXXXXXXXX

Ref: W037P0028

Exp: YYYY-MM-DD

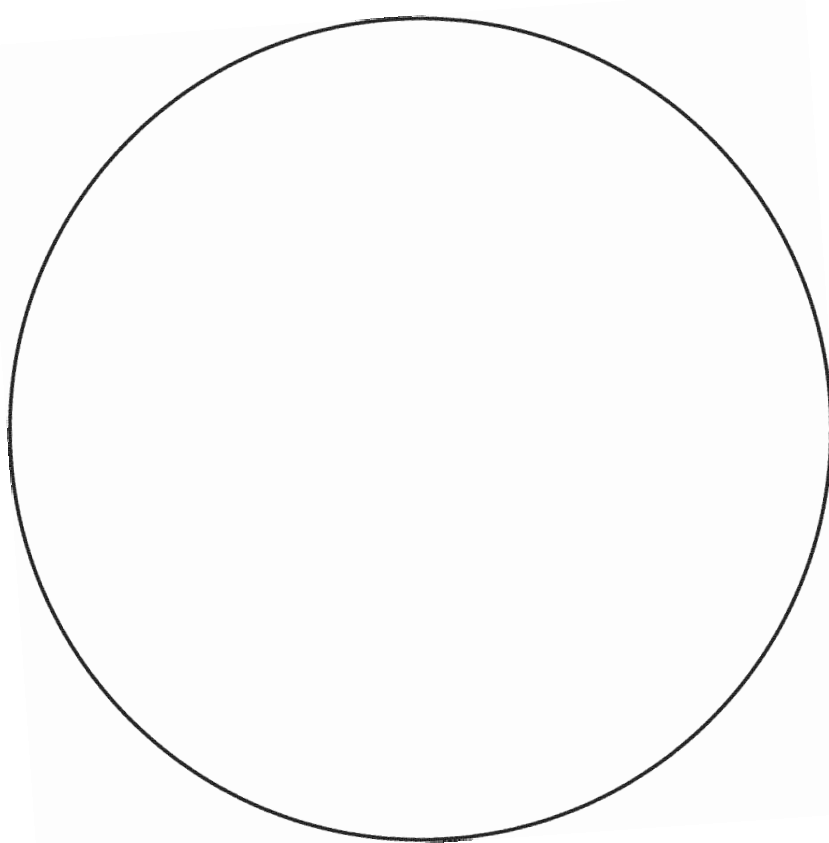
Vol:5ml

Store at:1-40°C

Version:A2

Rel.:2024/06/25

size:38\*20mm



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#### **1.4 Labels and packaging artwork for 25 T (W037P0030)**

# 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

Version: A3  
Rel.: 2024/06/25





 **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](http://en.wondfo.com)



 **Guangzhou Wondfo Biotech Co., Ltd.**  
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Tel: +86-20-32053962 Fax: +86-20-32296063  
Website: [en.wondfo.com](http://en.wondfo.com)



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



IVD

**We Are Working For Your Health**



距开口15mm



Wondfo Malaria P.f (HRP2/pLDH) Test

LOT XXXXXXXX  
REF W037P0030

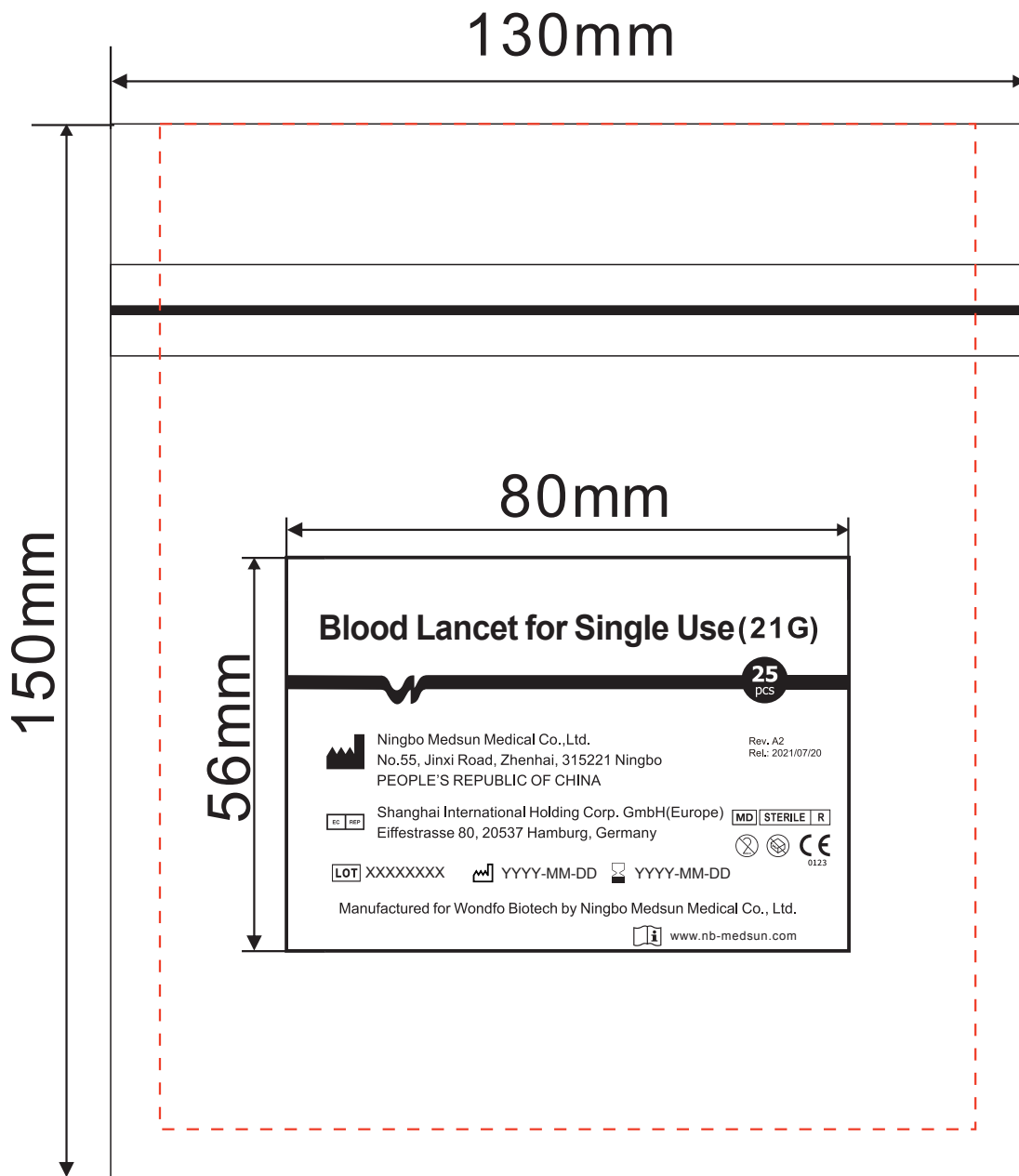
YYYY-MM-DD  
YYYY-MM-DD

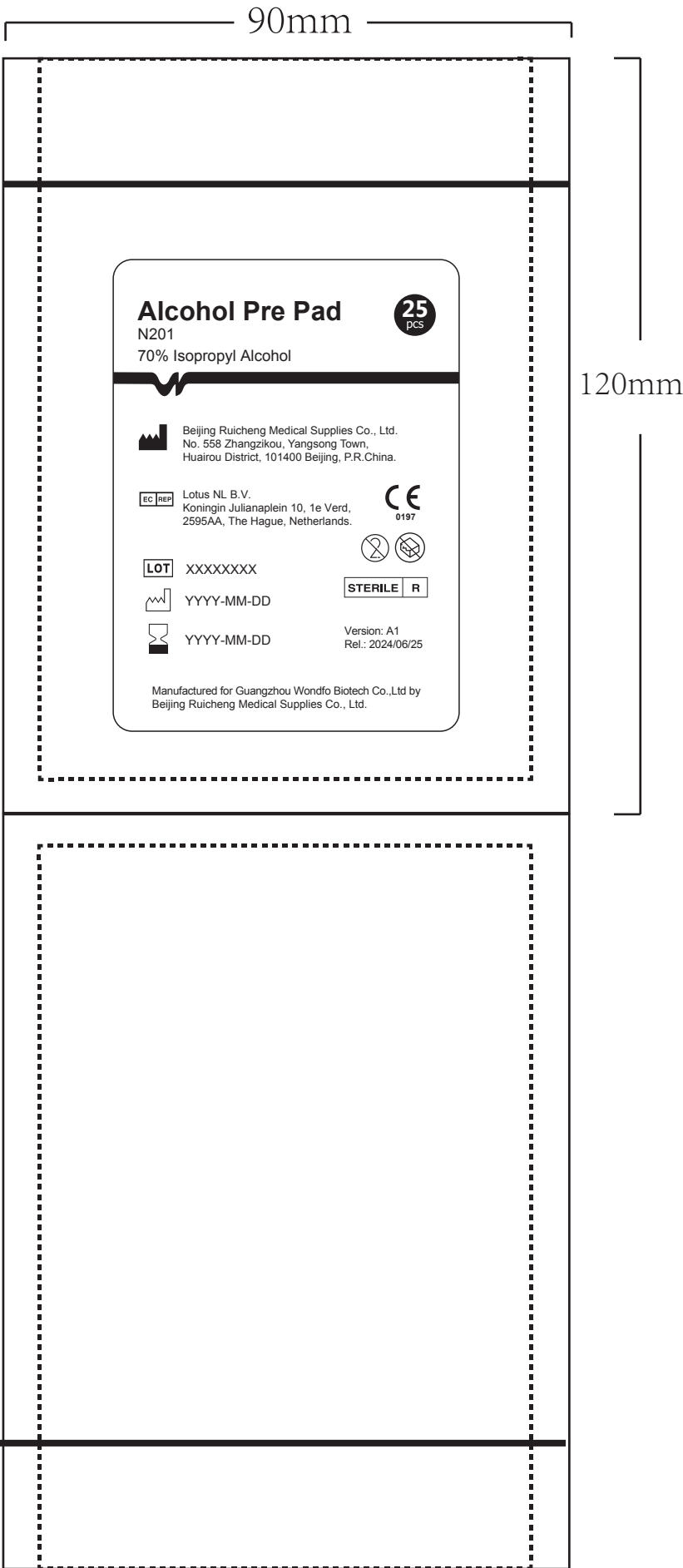
Version: A3  
Rel.: 2024/06/25

FOR IN VITRO DIAGNOSTIC USE ONLY



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





## Inverted cup



Foshan Nanhai Yuyang Plastic Mould Co., Ltd.  
No. 26, Honggang Industrial Zone, Lishui Town,  
Nanhai District, Foshan City

LOT

XXXXXXXX



YYYY-MM-DD



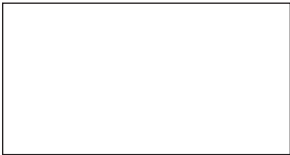
YYYY-MM-DD



25

Manufactured for Wondfo Biotech by  
Foshan Nanhai Yuyang Plastic Mould Co., Ltd.

Language: English  
Rev A2 Rel. 2021/11/18



size:38\*20mm

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

Lot: XXXXXXXXX

Ref: W037P0030

Exp: YYYY-MM-DD

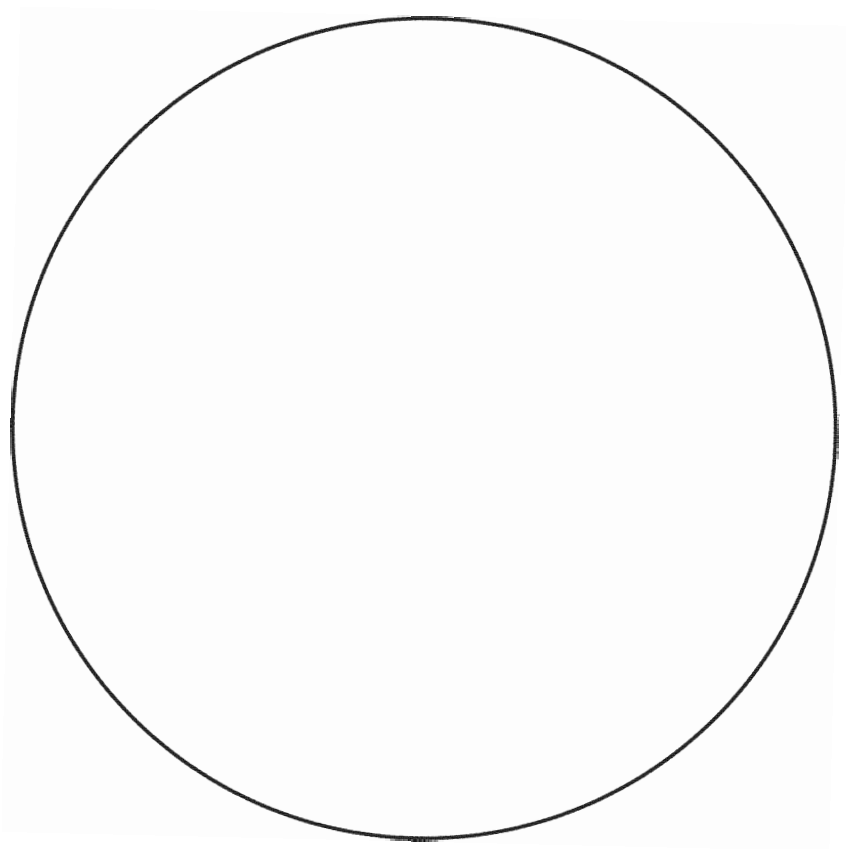
Vol:5ml









Store at:1-40°C

Version:A2

Rel.:2024/06/25

size:38\*20mm



<div><div></div><div><div>ART NO.:</div><div>C/NO.:</div><div>QTY: PCS</div><div>N.W: KGS</div><div>G.W: KGS</div><div>MEAS: 60×44×44 CM</div></div></div>		<div><div></div><div><div>ART NO.:</div><div>C/NO.:</div><div>QTY: PCS</div><div>N.W: KGS</div><div>G.W: KGS</div><div>MEAS: 60×44×44 CM</div></div></div>	



### **1.5 Labels and packaging artwork for 40 T (W037P0033)**

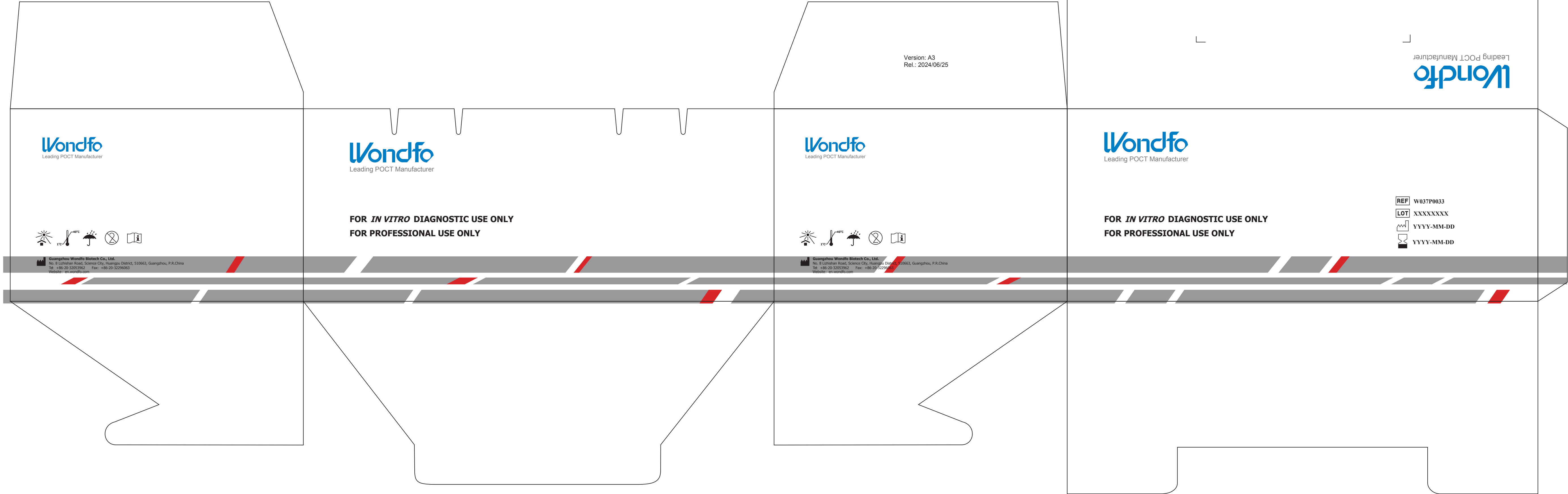
# Wondfo Malaria P.f (HRP2/pLDH) Test




## 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


Version: A2  
Rel.: 2024/06/25



距开口15mm



Leading POCT Manufacturer




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


LOT

XXXXXXXX

REF

W037P0033

 YYYY-MM-DD

 YYYY-MM-DD

Version: A3

Rel.: 2024/06/25

FOR *IN VITRO* DIAGNOSTIC USE ONLY



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

封口

成品：105x75mm 图案：54x65mm

10mm

95mm

15mm x 3mm

75mm

Sterile Lancet

40 pcs

Rev. A1  
Rel.: 2020/06/28

Beijing Ruicheng Medical Supplies Co., Ltd.  
No. 558 Zhangzikou, Yangsong Town, Huairou District,  
101400 Beijing, China

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

CE

0197

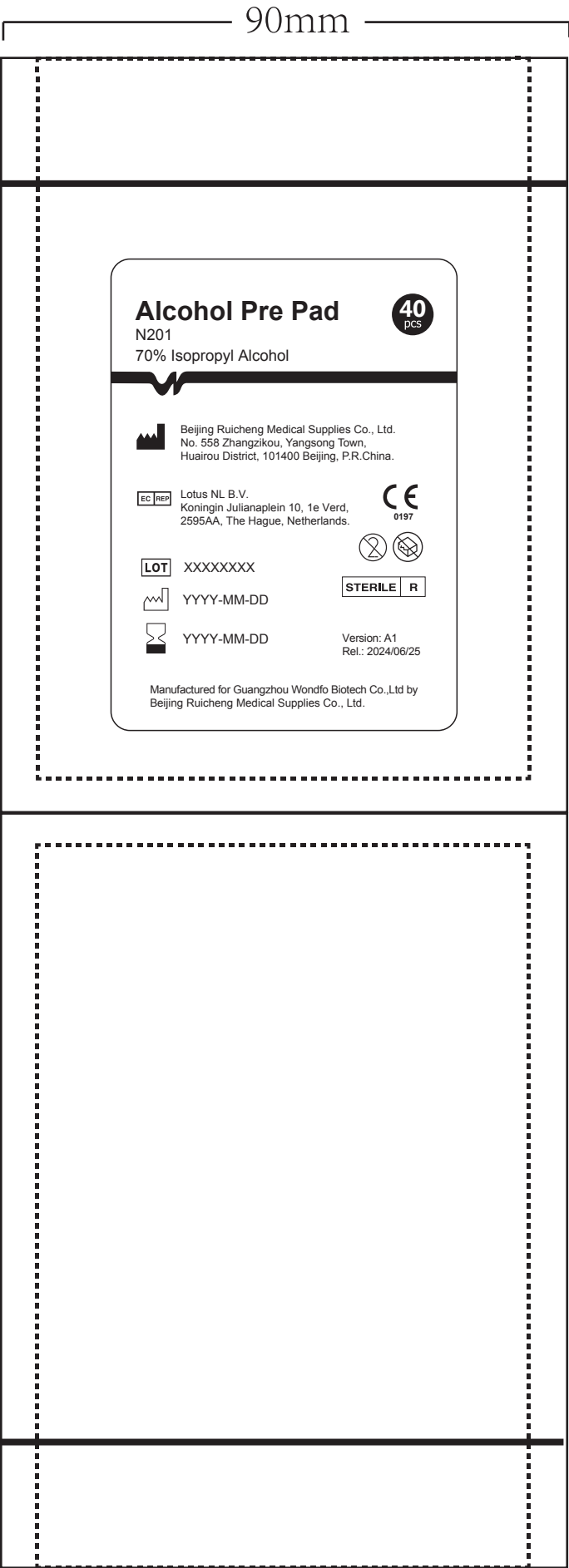
STERILE R

LOT XXXXXXXX

YYYY-MM-DD

YYYY-MM-DD

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



## Inverted cup



Foshan Nanhai Yuyang Plastic Mould Co., Ltd.  
No. 26, Honggang Industrial Zone, Lishui Town,  
Nanhai District, Foshan City

LOT

XXXXXXXX



YYYY-MM-DD



YYYY-MM-DD



40

Language: English  
Rev A2 Rel 2021/11/18

Manufactured for Wondfo Biotech by  
Foshan Nanhai Yuyang Plastic Mould Co., Ltd.



size:38\*20mm



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

Lot: XXXXXXXXX

Ref: W037P0033

Exp: YYYY-MM-DD

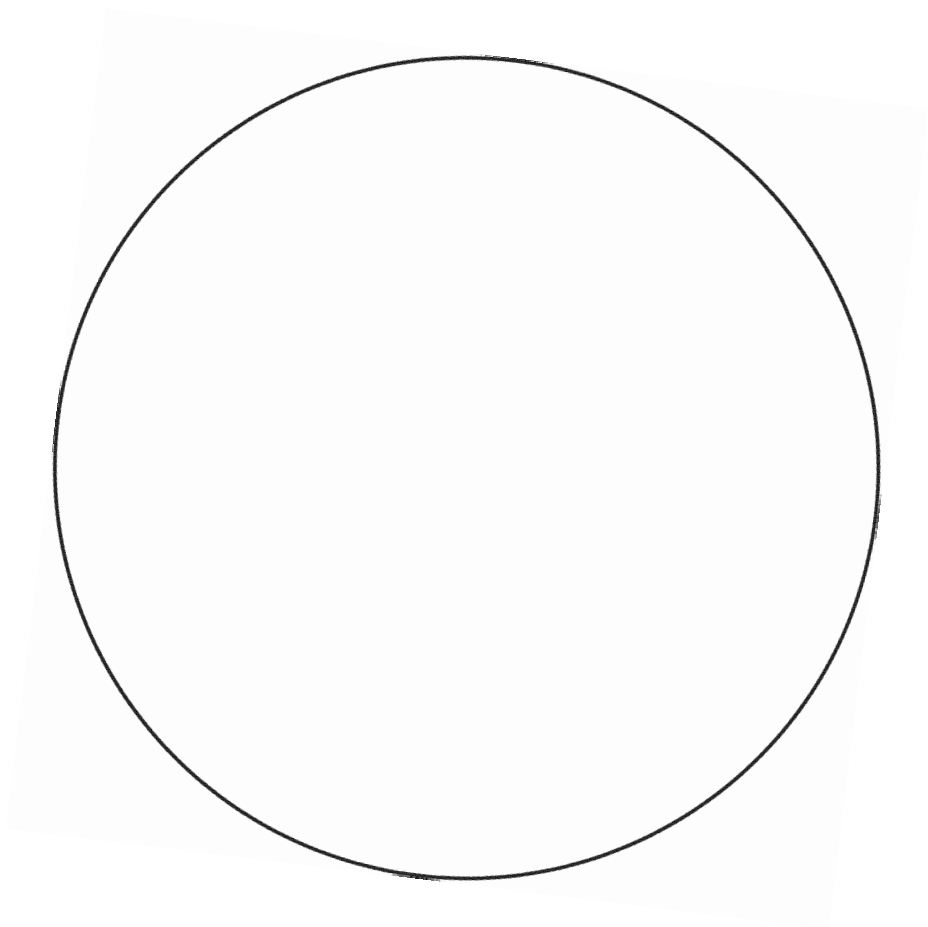
Vol:5ml

Store at:1-40°C

Version:A2

Rel.:2024/06/25

size:38\*20mm



380mm

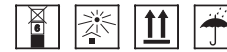


C/NO.:  
QTY: PCS  
N.W: KGS  
G.W: KGS  
MEAS: 63.0×50.0×38.0 CM

Version: 2017/01/22  
Rel.: 2017/02/09

500mm

630mm



C/NO.:  
QTY: PCS  
N.W: KGS  
G.W: KGS  
MEAS: 63.0×50.0×38.0 CM

Version: 2017/01/22  
Rel.: 2017/02/09

### **1.6 Labels and packaging artwork for 40 T (W037P0035)**

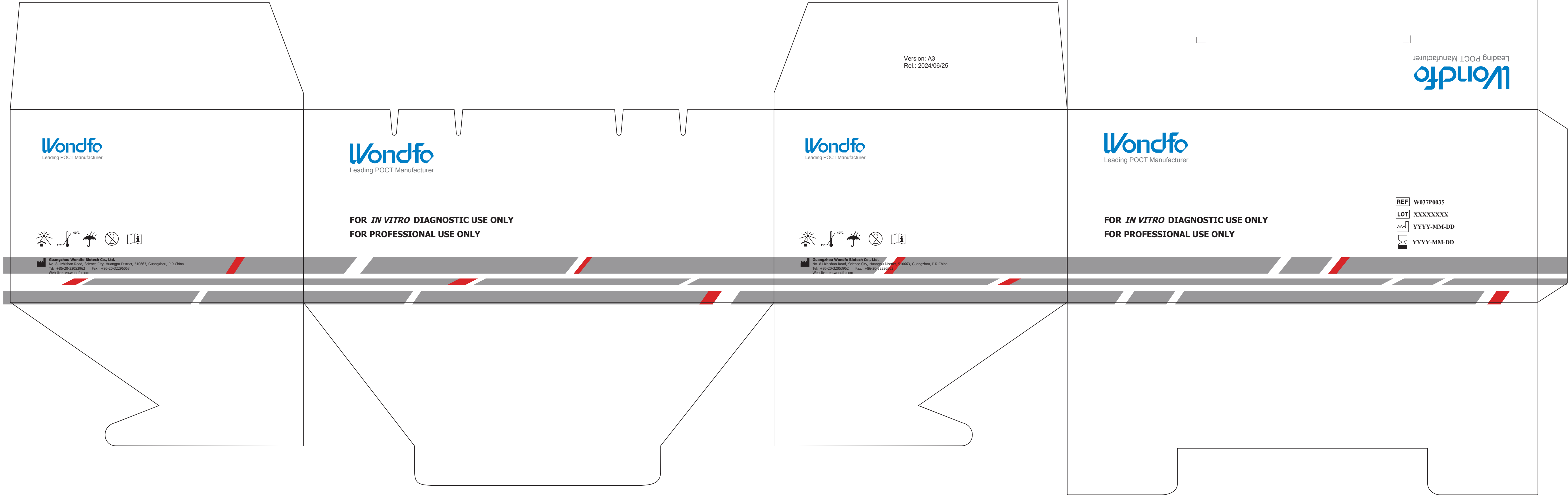
# Wondfo Malaria P.f (HRP2/pLDH) Test



## 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

Version: A3  
Rel.: 2024/06/25



**Wondfo**  
Leading POCT Manufacturer



Guangzhou Wondfo Biotech Co., Ltd.  
No. 8 Lishi 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

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

**Wondfo**  
Leading POCT Manufacturer



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

Version: A3  
Rel.: 2024/06/25

**Wondfo**  
Leading POCT Manufacturer

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

REF W037P0035  
LOT XXXXXXXX  
YYY-MM-DD  
YYY-MM-DD

**Wondfo**  
Leading POCT Manufacturer



WeAreWorkingForYour Health

距开口15mm



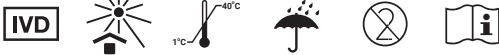
Wondfo **Malaria P.f (HRP2/pLDH) Test**

**LOT** XXXXXXXXX  
**REF** W037P0035

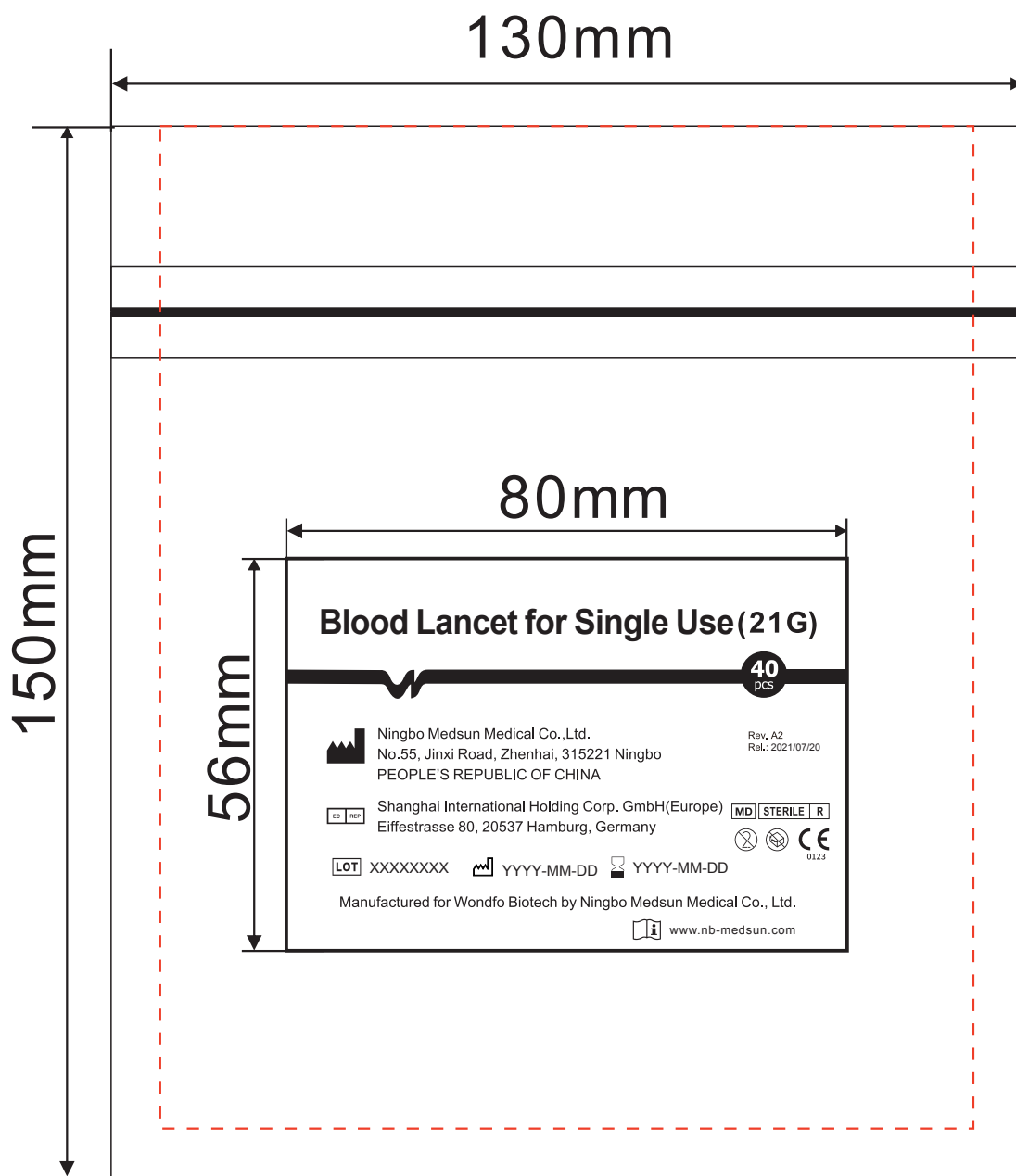
 XXXX-XX-XX  
 XXXX-XX-XX

Version: A3  
Rel.: 2024/06/25

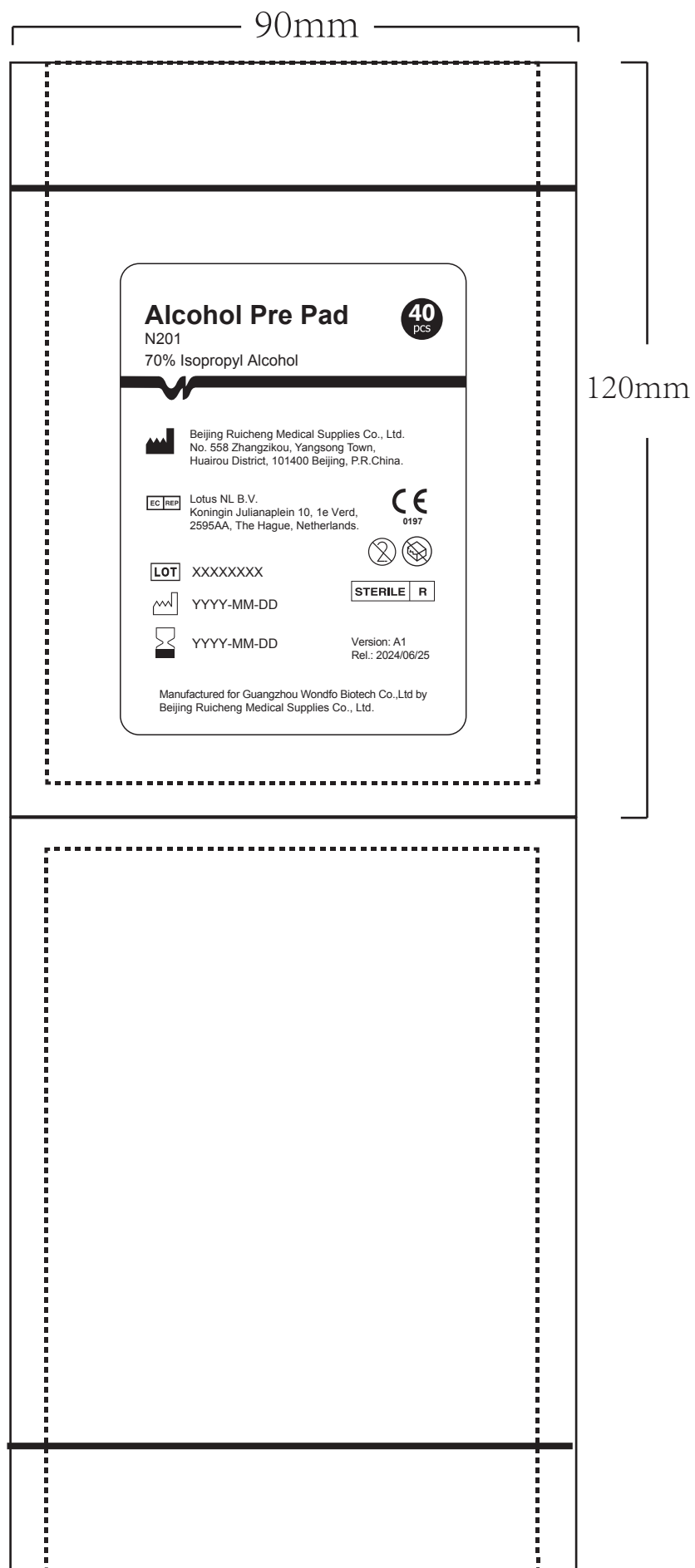
**FOR IN VITRO DIAGNOSTIC USE ONLY**



 **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







## Inverted cup



Foshan Nanhai Yuyang Plastic Mould Co., Ltd.  
No. 26, Honggang Industrial Zone, Lishui Town,  
Nanhai District, Foshan City



XXXXXXXX



YYYY-MM-DD

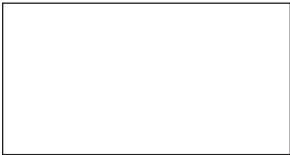


YYYY-MM-DD



Manufactured for Wondfo Biotech by  
Foshan Nanhai Yuyang Plastic Mould Co., Ltd.

Language: English  
Rev.A2 Rel.:2021/11/18



size:38\*20mm

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

Lot: XXXXXXXXX

Ref: W037P0035

Exp: YYYY-MM-DD

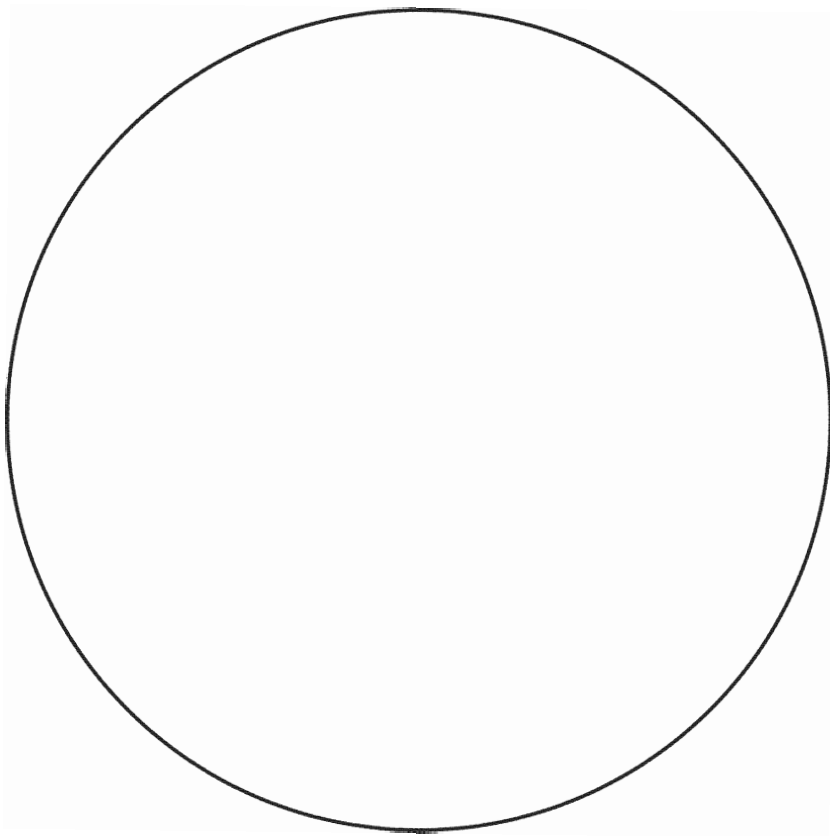
Vol:5ml

Store at:1-40°C

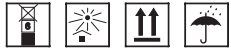
Version:A2

Rel.:2024/06/25

size:38\*20mm



380mm

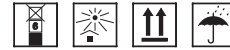


C/NO.:  
QTY: PCS  
N.W: KGS  
G.W: KGS  
MEAS: 63.0×50.0×38.0 CM

Version: 2017/01/22  
Rel.: 2017/02/09

500mm

630mm



C/NO.:  
QTY: PCS  
N.W: KGS  
G.W: KGS  
MEAS: 63.0×50.0×38.0 CM

Version: 2017/01/22  
Rel.: 2017/02/09

### **1.7 Labels and packaging artwork for 100 T (W037P0037)**

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

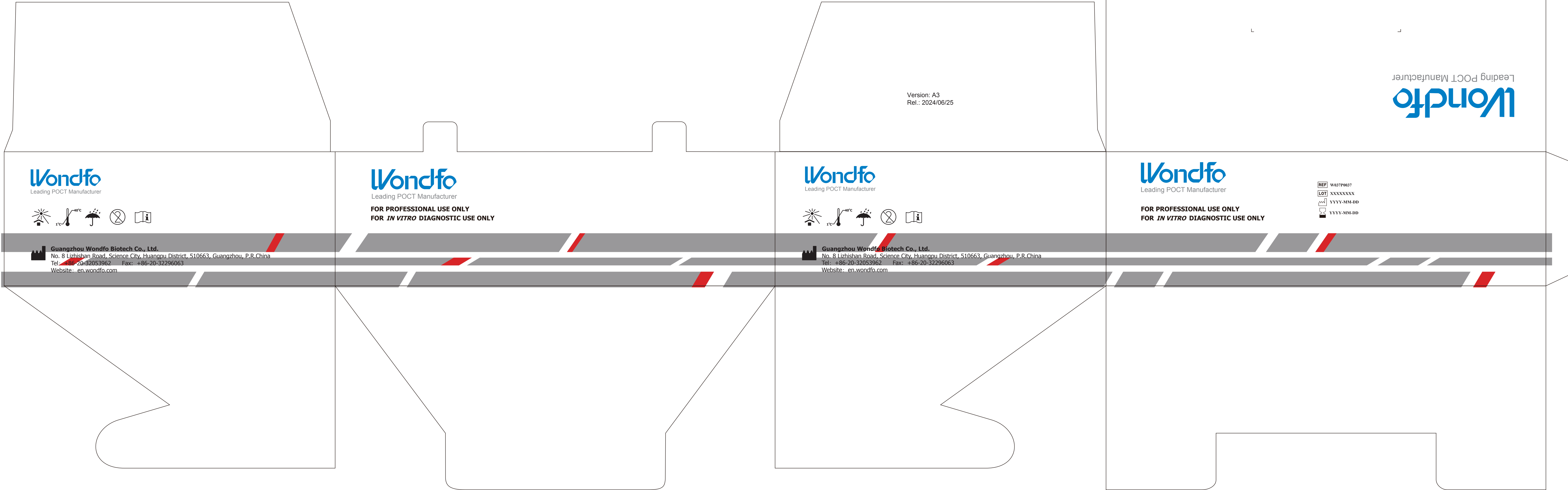


## CONTENTS:

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

Version: A2  
Rel.: 2024/06/25





**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

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

**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

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

REF: W037P0037  
LOT: XXXXXXXX  
EXP: YYYY-MM-DD  
EXP: YYYY-MM-DD


**Wondfo**  
Leading POCT Manufacturer


**IVD**

We Are Working For Your Health

Version: A3  
Rel.: 2024/06/25

距开口 15mm

  
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



IVD













Guangzhou Wondfo Biotech Co., Ltd.

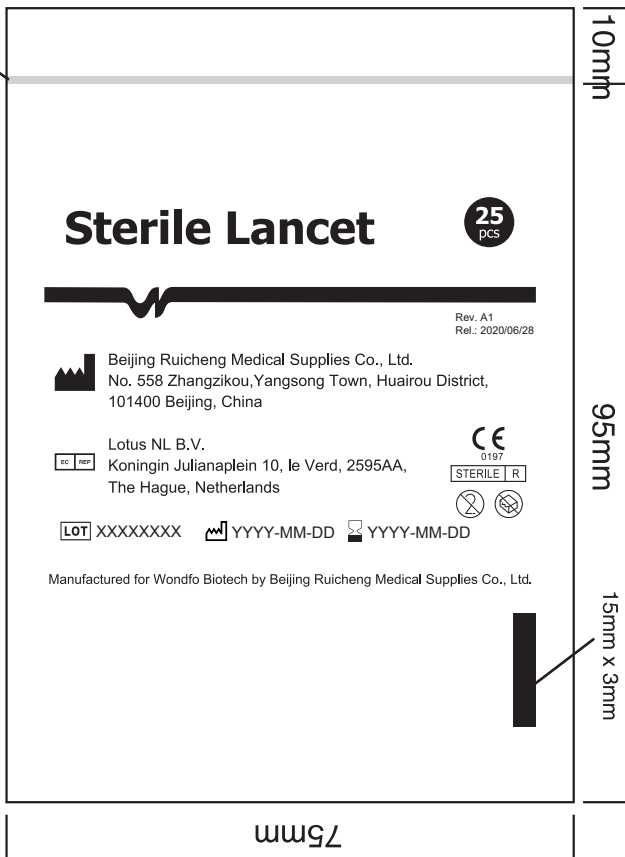
No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R.China

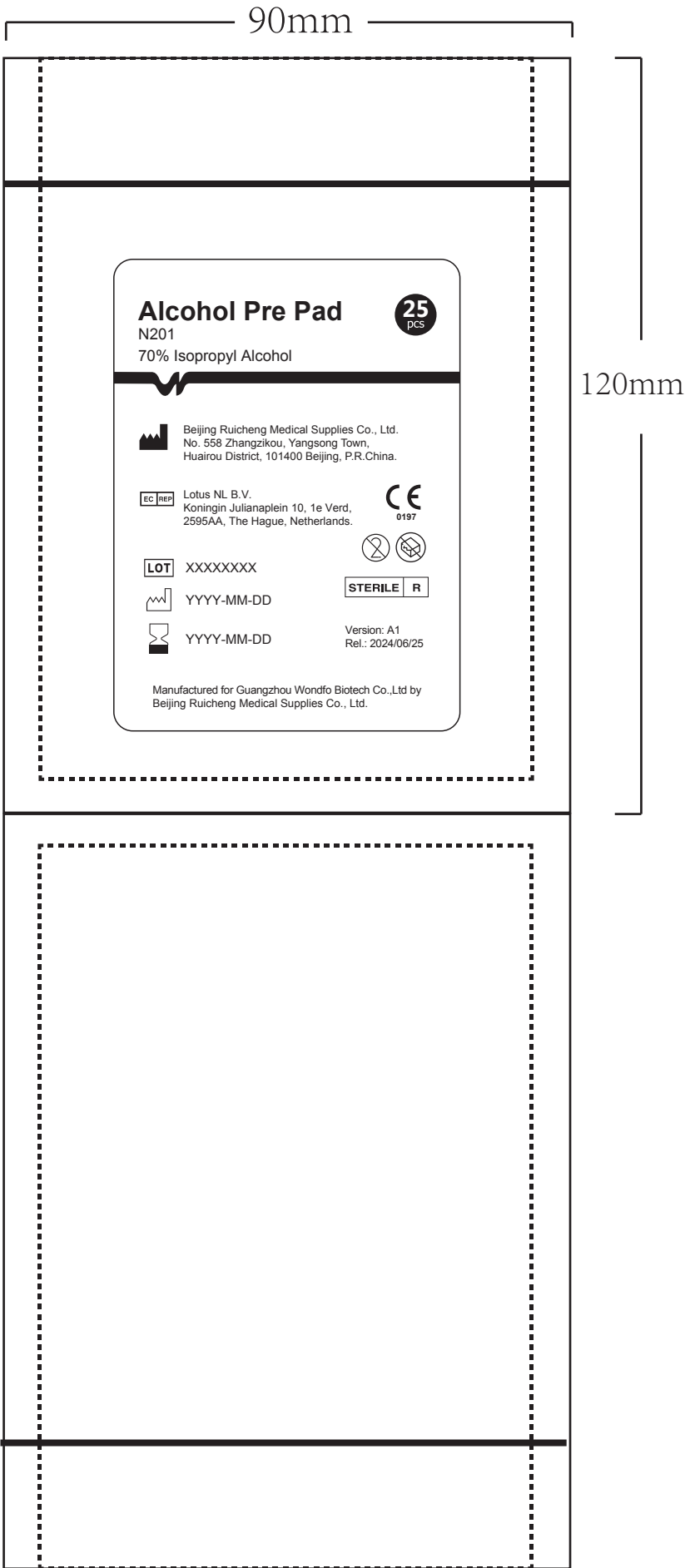
Tel: +86-20-32053962 Fax: +86-20-32296063

Website: en.wondfo.com

封口

成品：105x75mm 图案：54x65mm





## Inverted cup



Foshan Nanhai Yuyang Plastic Mould Co., Ltd.  
No. 26, Honggang Industrial Zone, Lishui Town,  
Nanhai District, Foshan City

LOT

XXXXXXXX



YYYY-MM-DD



YYYY-MM-DD



25

Manufactured for Wondfo Biotech by  
Foshan Nanhai Yuyang Plastic Mould Co., Ltd.

Language: English  
Rev A2 Rel. 2021/11/18



size:38\*20mm

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

Lot: XXXXXXXXX

Ref: W037P0037

Exp: YYYY-MM-DD

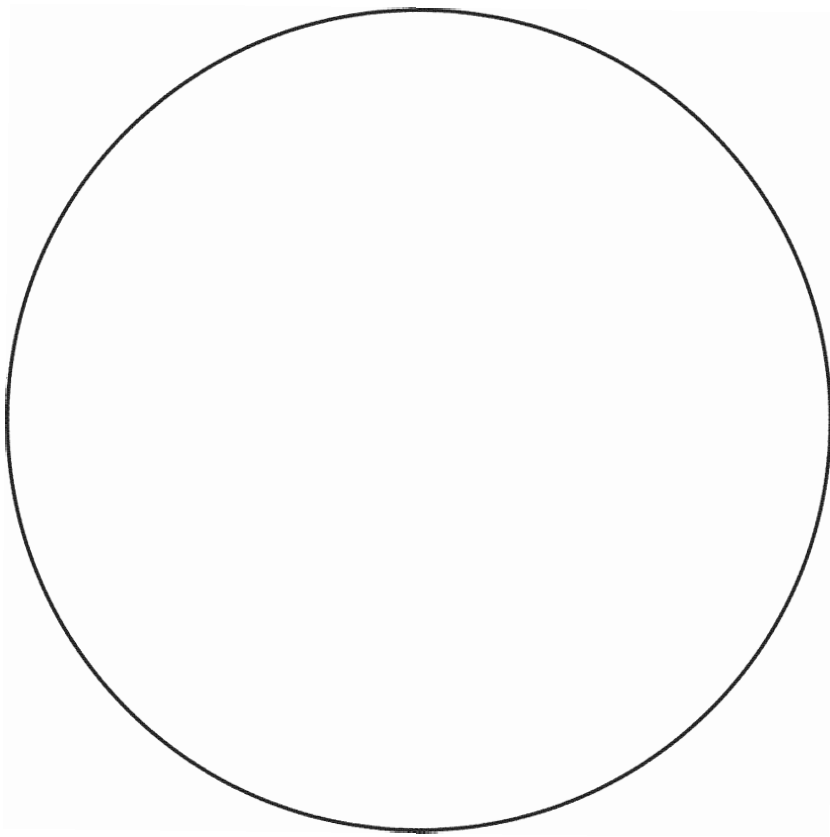
Vol:5ml

Store at:1-40°C









Version:A2

Rel.:2024/06/25

size:38\*20mm





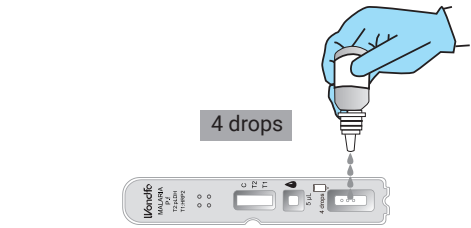
	<div><div></div><div>ART NO.: C/NO.: QTY: PCS N.W: KGS G.W: KGS MEAS: 61×46.4×48.4 CM</div></div>		<div><div></div><div>ART NO.: C/NO.: QTY: PCS N.W: KGS G.W: KGS MEAS: 61×46.4×48.4 CM</div></div>

## **2.1 Instructions for use<sup>2</sup>**

---

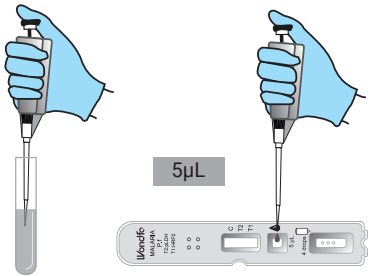
<sup>2</sup> English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.



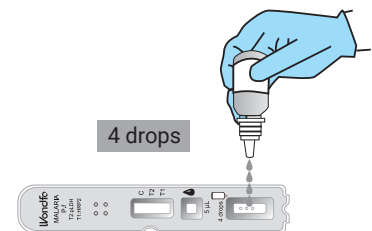


## 2. Test procedure for venous whole blood

- 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)		<b>Result: Invalid.</b> 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		<b>Result: Negative.</b> Action: No
-------------------------------	--	--

Lines that you see	Picture	Read and Interpretation of Results
--------------------	---------	------------------------------------

Line at 'C' and at 'T1' and/or 'T2'	1	<b>Result: Positive.</b> 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	

**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

- 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.
- Strictly operate according to the instructions for use when testing. False operation will result in a false result.
- Use EDTA, heparin sodium, and sodium citrate as anticoagulants. Do not use other anticoagulants.
- 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.
- 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.
- 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.
- 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<sup>[2,3]</sup>

### 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	354	357	Specificity:99.16% (97.56~99.71%)
Rwanda	P.f Positive	175	0	175	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% (98.51~99.95%)

\*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 Pf (HRP2/pLDH) Test	SD Bioline		Test Result (95% CI)	
		Venous whole blood			
		Positive	Negative		
Cameroon	Venous whole blood	Positive	26	0	Sensitivity: 100% (87.13%-100.00%)
		Negative	0	30	Specificity: 100% (88.65%-100.00%)
	Fingerstick whole blood	Positive	26	0	Sensitivity: 100% (87.13%-100.00%)
		Negative	0	30	Specificity: 100% (88.65%-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

- 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.
- The following potential interfering substances have no impact on Wondfo Malaria P. f (HRP2/ pLDH) Test.

No.	Type	Interfering substances
1	Antigen	HAMA
2		Recipient of multiple blood transfusion
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	Endogenous	Triglyceride
12		Human Chorionic Gonadotropin
13		Cholesterol
14		Low density lipoprotein
15		Haemoglobin
16		Direct bilirubin
17		Chloroquine Phosphate
18		Artemisinin
19		Amoxicillin
20		Cefalexin
21	Exogenous	Doxycycline Hyclate
22		Erythromycin
23		Ibuprofen
24		Piperaquine
25		Mebendazole
26		Tribendimidine
27		Entecavir
28		Rifampicin
29		Aspirin
30		Paracetamol
31		Ethanol
32		Caffeine

- 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	Antibody	Toxoplasma gondii
12		Plasmodium vivax
13		HAV
14		Measles
15		Influenza
16		Tick borne encephalitis
17		Rubella-IgG
18		Dengue Virus IgG
19		Cytomegalovirus-IgG

- 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.

## REFERENCES

- WHO. World Malaria Report 2019, Geneva: World Health Organization; 2019.
- WHO.TSS-3 Malaria rapid diagnostic tests, Geneva: World Health Organization; 2017.
- WHO. TGS-5 Designing instructions for use for in vitro diagnostic medical devices, Geneva: World Health Organization; 2017.
- WHO. Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTs: round 7 (2015-2016), Geneva: World Health Organization; 2017.
- WHO. Global technical strategy for malaria

2016–2030, Geneva: World Health Organization; 2015.

## SYMBOLS KEY

	In vitro diagnostic medical device		Consult instructions for use		Use-by date
	Contains sufficient for <n> tests		Date of manufacture		Keep dry
	Batch code		Caution		Keep away from sunlight
	Manufacturer		Do not re-use		Catalogue number
	Temperature limit				

## 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: +86-20-32296063  
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.

Language:English

IFU Version Information		
Rev. A6 (Valid version)	Rel.: 2024/9/5	Minor changes in the limitations of the test and changes in the performance characteristics section.
Rev. A5	Rel.: 2023/12/22	Supplementation of intended testing population in intended use section and changes in the performance characteristics section.
Rev. A4	Rel.: 2021/12/16	Supplementation of clinical data in performance characteristics section.
Rev. A3	Rel.: 2021/9/30	Adjustment of product configurations in kit component section.
Rev. A2	Rel.: 2021/6/18	Supplementation of clinical data in performance characteristics section
Rev. A1	Rel.: 2020/7/27	Original version.



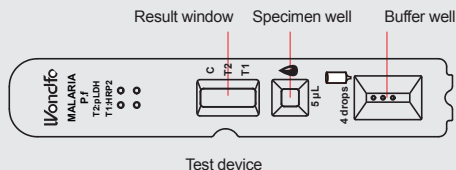
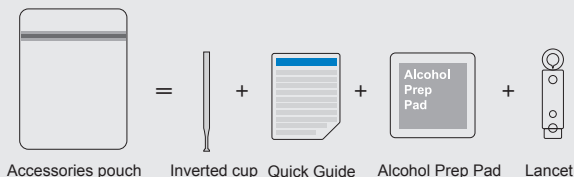
## **2.2 Quick User Guide**

## QUICK GUIDE

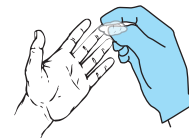
For fingerstick whole blood

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.

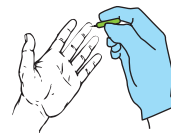
### Material provided



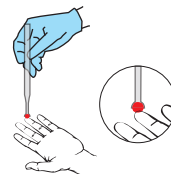
- 1 Wash hands and put on protective gloves before testing. Wipe the fingertip to be lanced with an alcohol prep pad. Select the middle or ring finger for sampling and avoid calloused areas of the finger.



- 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.

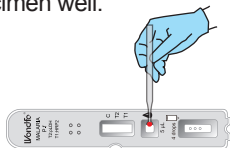


- 3 Dip the circular end of the inverted cup into the blood specimen (5µL).



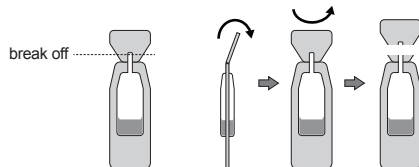
**!** Fingerstick whole blood should be tested immediately.

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

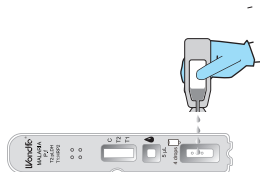


**!** Do not add into buffer well.

- 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)		<b>Result: Invalid.</b> 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		<b>Result: Negative.</b> Action: No
Line at 'C' and at 'T1' and/or 'T2'		<b>Result: Positive.</b> 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

## DISPOSE

**!** IMPORTANT

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

