WHO Prequalification of In Vitro Diagnostics
PUBLIC ASSESSMENT REPORT

Product: Wondfo HIV Self-Test
WHO reference number: PQDx 0357-004-01

Wondfo HIV Self-Test with product codes W006P0058, W006P0059, W006P0060**,** and W006P0079, manufactured by Guangzhou Wondfo Biotech Co., Ltd, Rest-of-World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 13 July 2022.

Summary of WHO's Prequalification Assessment for the Wondfo HIV Self-Test[1]

	Date	Outcome
Prequalification listing for the Wondfo HIV Self-Test	13 July 2022	Listed
Prequalification listing for the One Step HIV1/2 Whole Blood/Serum/Plasma Test	29 November 2018	Listed
Dossier assessment	26 April 2018	MR
Product performance evaluation	First-quarter of 2018	MR

MR: Meets Requirements

***Change notification**

In 2021, Guangzhou Wondfo Biotech Co., Ltd submitted a change notification for their prequalified product, One Step HIV1/2 Whole Blood/Serum/Plasma Test, to introduce a new configuration with an intended use specific for HIV self-testing (Wondfo HIV Self-Test). The new format was adapted from the corresponding professional-use product (One Step HIV1/2 Whole Blood/Serum/Plasma Test), for which a WHO prequalification assessment has already been completed. Guangzhou Wondfo Biotech Co., Ltd generated additional data to meet requirements for self-testing as set out in the WHO Technical Specifications Series document TSS-1 Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and self-testing[2].

[1] Dossier assessment and product performance evaluation for the Wondfo HIV Self-Test were considered from the previous assessment of professional use product, One Step HIV1/2 Whole Blood/Serum/Plasma Test, which was prequalified in 2018. Based on the product dossier assessment and product performance evaluation, Wondfo HIV Self-Test meets WHO prequalification requirements. Please refer to https://extranet.who.int/prequal/WHOPR/public-report-one-step-hiv12-whole-bloodserumplasma-test-pqdx-0357-004-00

[2] https://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf;jsessionid=153ABC9D88E7623A1AD1DF946A22B4C8?sequence=1

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.

Public report amendment	**Summary of amendment and change request reference, where applicable.**	**Date of report amendment**
2.0	Added local languages to IFU. The changes included: 1. The length of the box for W006P0059(20T/kit) increased by 2 cm, from 230X185X105mm to 250X185X105mm; another artwork of the box has not changed. 2. Two optional sizes of IFU, the prequalified 420*285 mm and the additional 570*420 mm.	19 July 2024
3.0	Change the section 'PERFORMANCE CHARACTERISTICS' of the current Instructions for Use by supplementing clinical evaluation data obtained from healthcare professionals. Addition of Portuguese to the multilingual IFU (PQC-IVD-2025-0002). New configuration containing a disposable bag and plaster. Addition of French and Portuguese to the labels (PQC-IVD-2025-0063).	15 January 2026

Intended use:

According to the intended use claim from Guangzhou Wondfo Biotech Co., Ltd, "*the Wondfo HIV Self-Test is a single-use in vitro diagnostic self-test for fingerstick whole blood detection of HIV-1/2. It is intended to be used as a self-test and/or by medical professionals. For in vitro diagnostic use only."*

Test kit contents

Components \ Catalog No.		W006P0058	W006P0059	W006P0060	W006P0079
Test cassette pouch	Test cassette (pcs)	1	1x20	1x100	1x20
	Desiccant (pcs)	1	1x20	1x100	1x20
Accessories	Dropper (pcs)	1	1x20	1x100	1x20
	Buffer (vial)	1	1x20	1x100	1x20
	IFU (pcs)	1	1x20	1x100	1x20
	Blood Lancet for Single Use (pcs)	1	1x20	1x100	1x20
	Alcohol prep pad (pcs)	1	1x20	1x100	1x20
	Cotton swab (pcs)	1	1x20	1x100	1x20
	Disposal bag (pcs)	1	/	/	1x20
	Plaster (pcs)	/	/	/	1x20

Materials required but not provided:

- Timer
- Tissue

Storage

The test kit must be stored between 2 and 30 °C.

Shelf-life upon manufacture[3]

24 months (test kit and buffer).

Labelling review

The labelling submitted for the Wondfo HIV Self-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.

[3] 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.

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

Catalog No.	Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
W006P0058	**Outer box artwork**	Box artwork	A5	2025/03/25	DLA-W006(3)-01-01
	Pouch / Device label	Foil pouch	A4	2025/03/25	DAT-W006(3)-01-01
	Test cassette foil pouch	Test cassette foil pouch	A3	2023/03/31	DLC-W006(3)-01-01
	Accessory labeling (e.g., pipettes, buffer caps)	Accessories pouch	A2	2025/03/25	DAV-W006(3)-01-01
W006P0059	**Outer box artwork**	Box artwork	230*185*105mm: A2; 250*185*105mm: A1	2023/03/31 ; 2025/03/25	DLA-W006(3)-01-02
	Outer box label	Box label	A5	2025/03/25	DLB-W006(3)-01-02
	Pouch / Device label	Foil pouch	A4	2025/03/25	DAT-W006(3)-01-02
	Test cassette foil pouch	Test cassette foil pouch	A3	2023/03/31	DLC-W006(3)-01-02
	Accessory labeling (e.g., pipettes, buffer caps)	Same as W006P0058			
W006P0060	**Outer box artwork**	Box artwork	/	/	DLA-W006(3)-01-03
	Outer box label	Box label	A4	2025/03/25	DLB-W006(3)-01-03
	Pouch / Device label	Foil pouch	A4	2025/03/25	DAT-W006(3)-01-03
	Test cassette foil pouch	Test cassette foil pouch	A3	2023/03/31	DAV-W006(3)-01-01
	Accessory labeling (e.g., pipettes, buffer caps)	Same as W006P0058			

W006P0079	**Outer box artwork**	Box artwork	A1	2023/03/31	DLA-W006(3)-01-04
	Outer box label	Box label	A5	2025/03/25	DLB-W006(3)-01-04
	Pouch / Device label	Foil pouch	A4	2025/03/25	DAT-W006(3)-01-04
	Test cassette foil pouch	Test cassette foil pouch	A3	2023/03/31	DLC-W006(3)-01-04
	Accessory labeling (e.g., pipettes, buffer caps)	Same as W006P0058			
/	**Instructions for Use**	IFU	A8	2025/05/28	IFU-W006(3)-01-01

Labels

1.1 Labels for product code W006P0058

Rev. A5 Rel.: 2025/03/25

Wondfo

Leading POCT Manufacturer

EN
CONTENTS:
1 Test cassette
1 Desiccant pouch
1 Instruction for use
1 Buffer
1 Dropper
1 Alcohol prep pad
1 Blood Lancet for Single Use
1 Cotton swab
1 Disposal bag
(W006P0058, W006P0079 ONLY)

FR
CONTENUS:
1 Cassette de test
1 Sachet de déshydratant
1 Mode d'emploi
1 Solution tampon
1 Compte-gouttes
1 Tampon alcoolisé
1 Lancette à usage unique
1 Coton-tige
1 Sac poubelle
(W006P0058, W006P0079 UNIQUEMENT)

PT
CONTEÚDO:
1 Cassete de teste
1 Bolsa dessecante
1 Instruções de utilização
1 Tampão
1 Conta-gotas
1 Toalhete desinfectante
1 Lanceta de Utilização Única
1 Cotonete de algodão
1 Bolsa de descarte
(W006P0058, W006P0079 APENAS)

REF W006P0058
LOT WXXXXXXXXX
YYYY-MM-DD
YYYY-MM-DD

6 933289 809108

2°C 30°C

Wondfo

Leading POCT Manufacturer

Wondfo HIV Self-Test

FOR *IN VITRO* DIAGNOSTIC USE ONLY
FOR SELF-TESTING USE

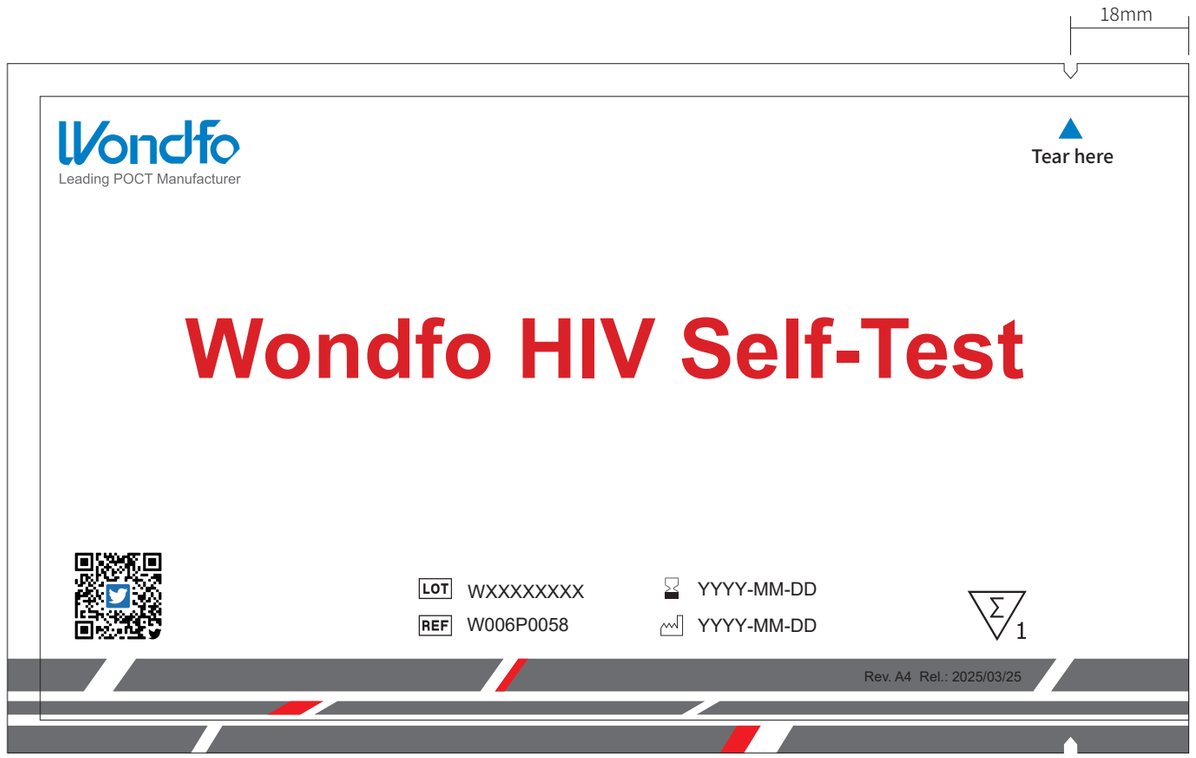
Σ 1 IVD

Wondfo
Leading POCT Manufacturer

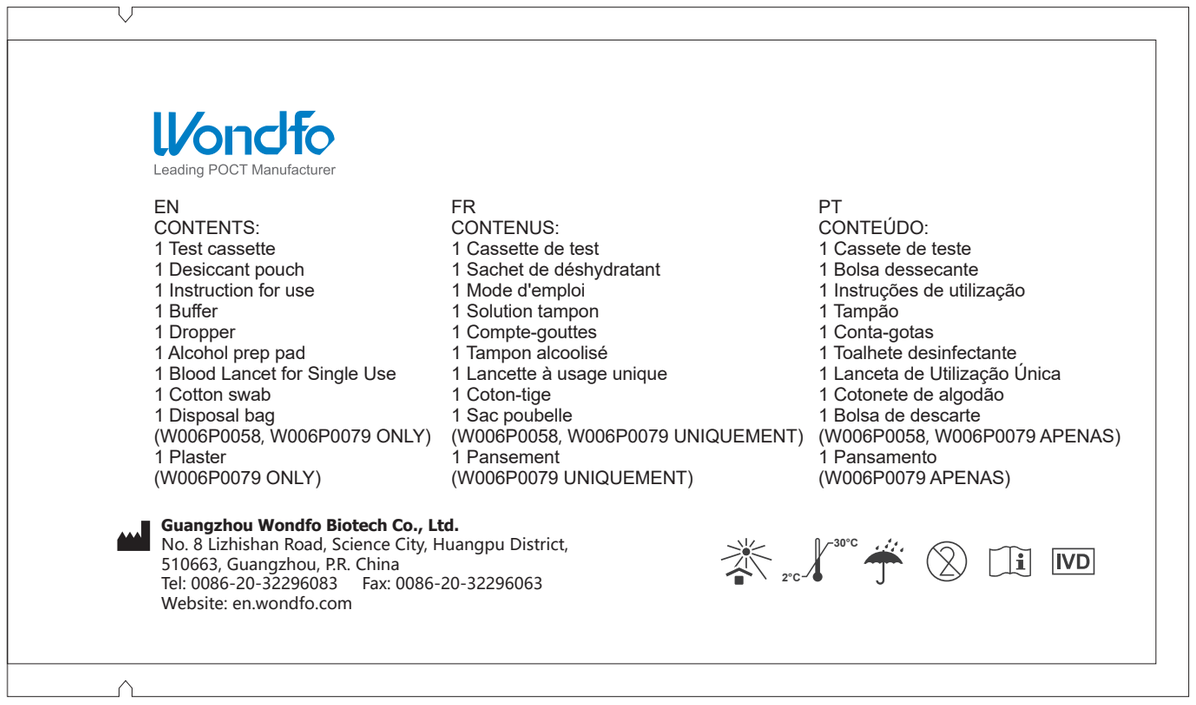
Guangzhou Wondfo Biotech Co., Ltd.
Add:No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R. China
Tel:0086-20-32296083 Fax:0086-20-32296063 Website: en.wondfo.com

Note: The lot number have three formats. Format 1 is WXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXX which is ten characters, and format 3 is WXXXXXXX which is nine characters.

Front



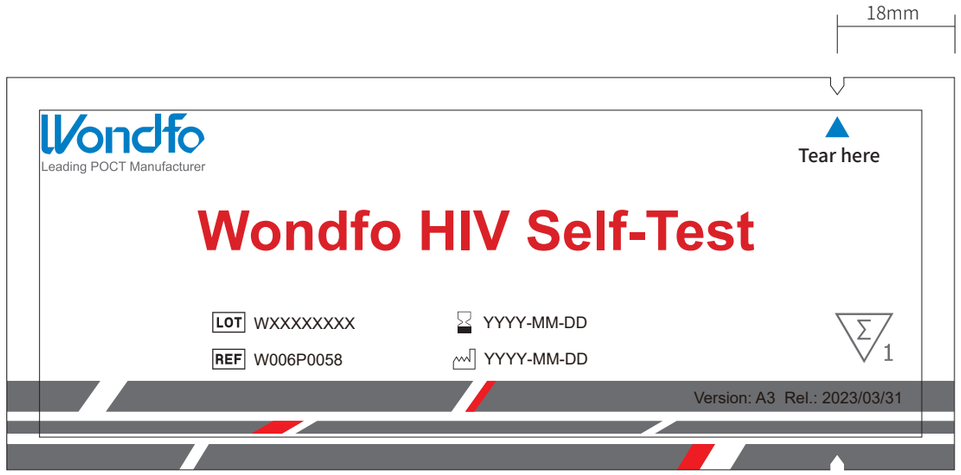
Back



Foil Pouch for W006P0058

Note: The lot number have three formats. Format 1 is WXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXX which is ten characters, and format 3 is WXXXXXXX which is nine characters.

Front



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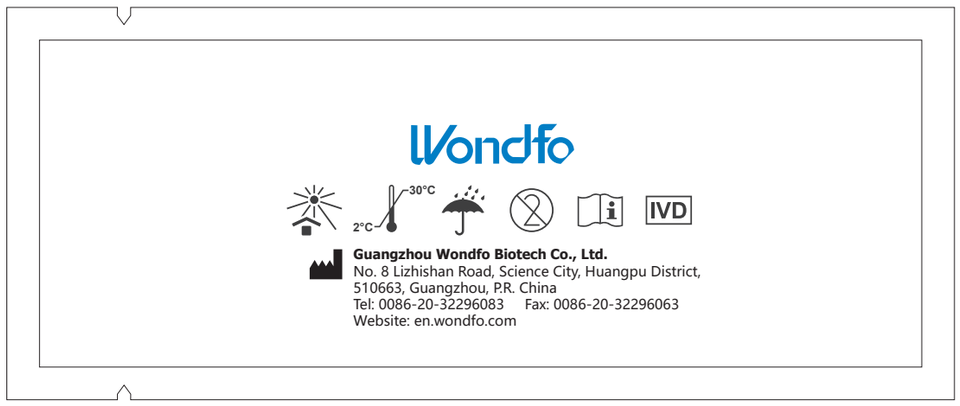
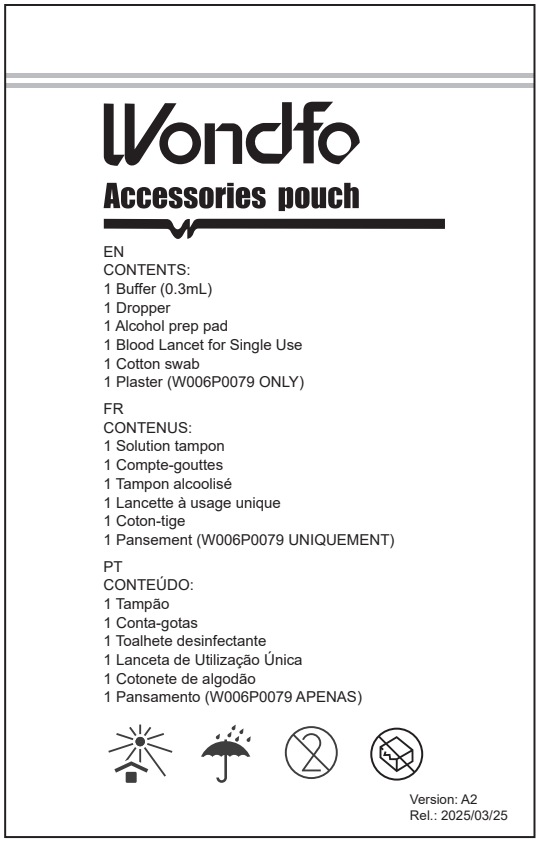


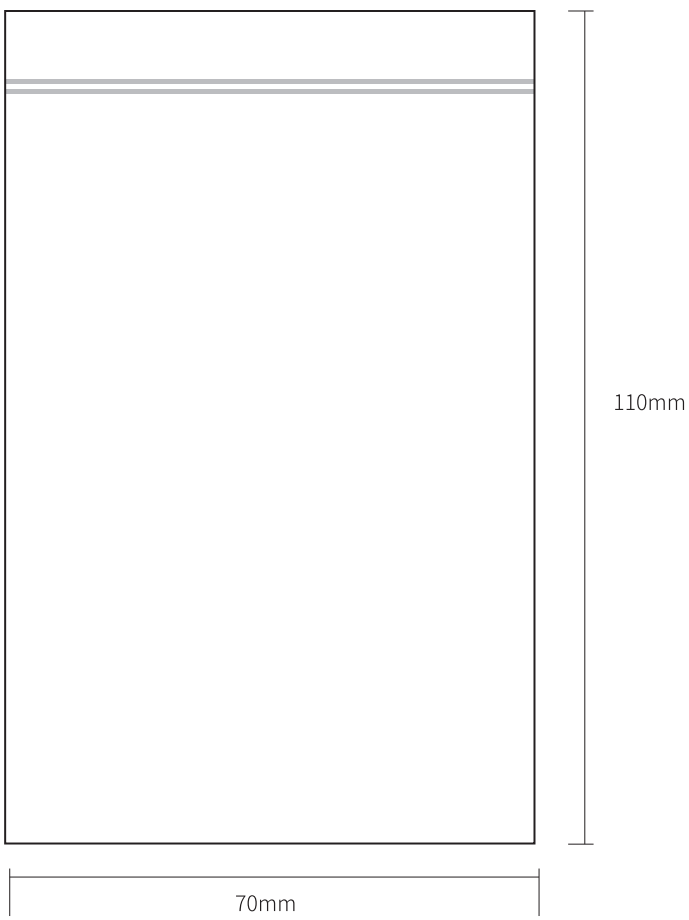
Test Cassette Foil Pouch for W006P0058

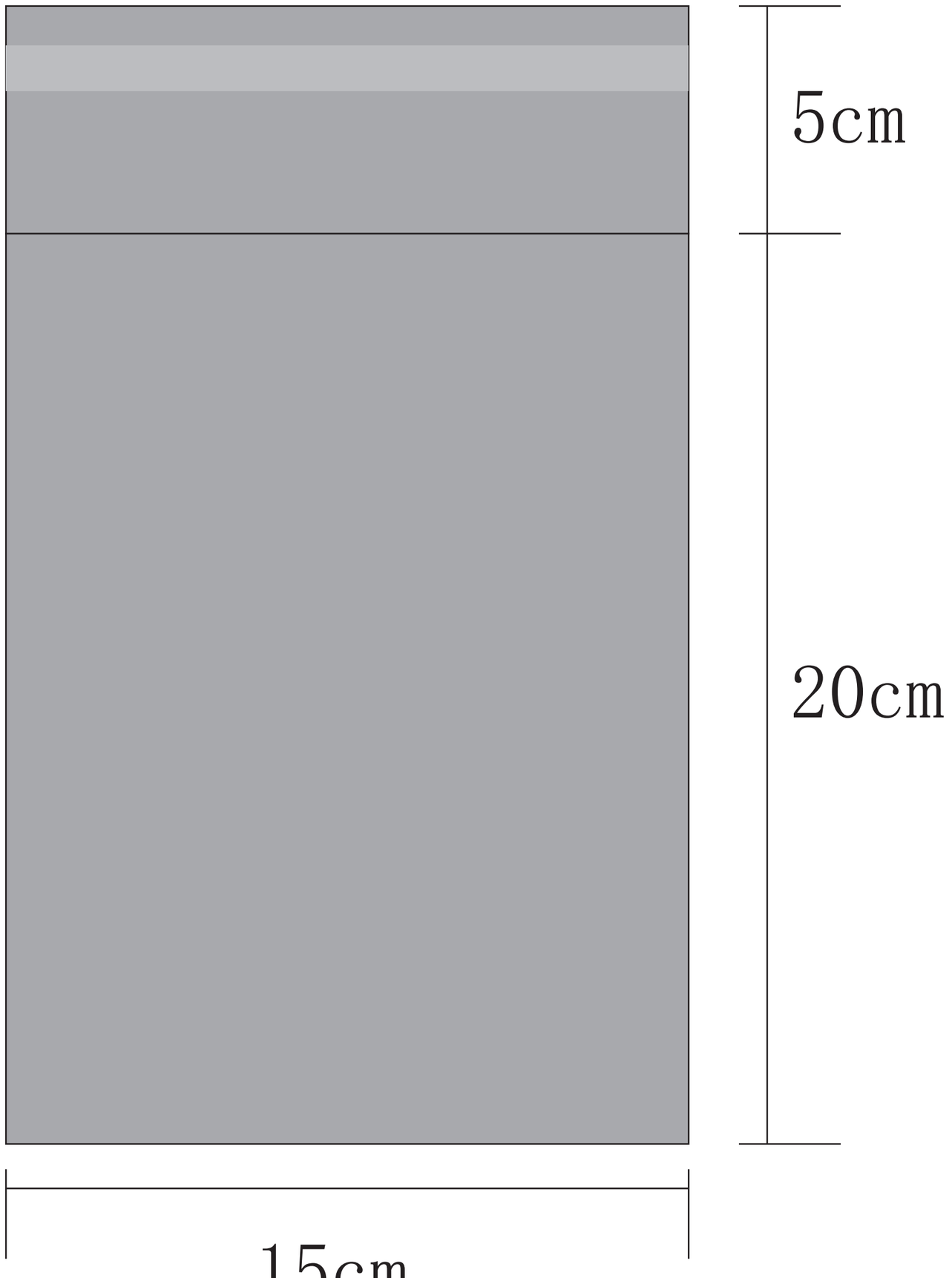
Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.

Front

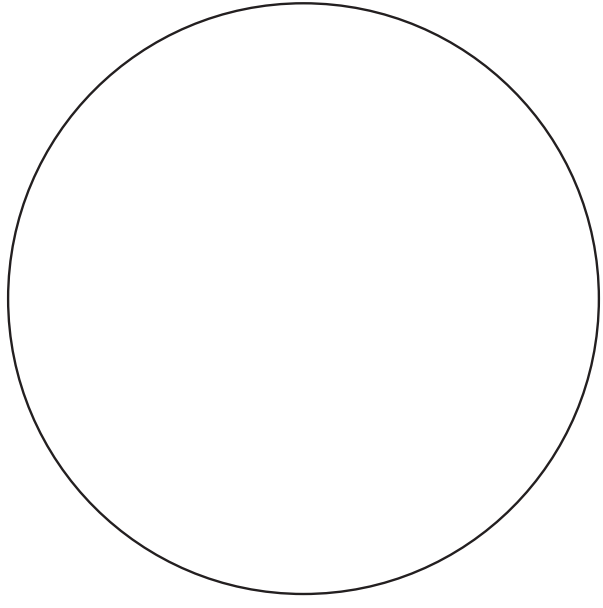

10mm
Wondfo
Accessories pouch
EN
CONTENTS:
1 Buffer (0.3mL)
1 Dropper
1 Alcohol prep pad
1 Blood Lancet for Single Use
1 Cotton swab
1 Plaster (W006P0079 ONLY)
FR
CONTENUS:
1 Solution tampon
1 Compte-gouttes
1 Tampon alcoolisé
1 Lancette à usage unique
1 Coton-tige
1 Pansement (W006P0079 UNIQUEMENT)
PT
CONTEÚDO:
1 Tampão
1 Conta-gotas
1 Toalhete desinfectante
1 Lanceta de Utilização Única
1 Cotonete de algodão
1 Pansamento (W006P0079 APENAS)
Version: A2
Rel.: 2025/03/25

Back


110mm
70mm



Disposal Bag for W006P0058

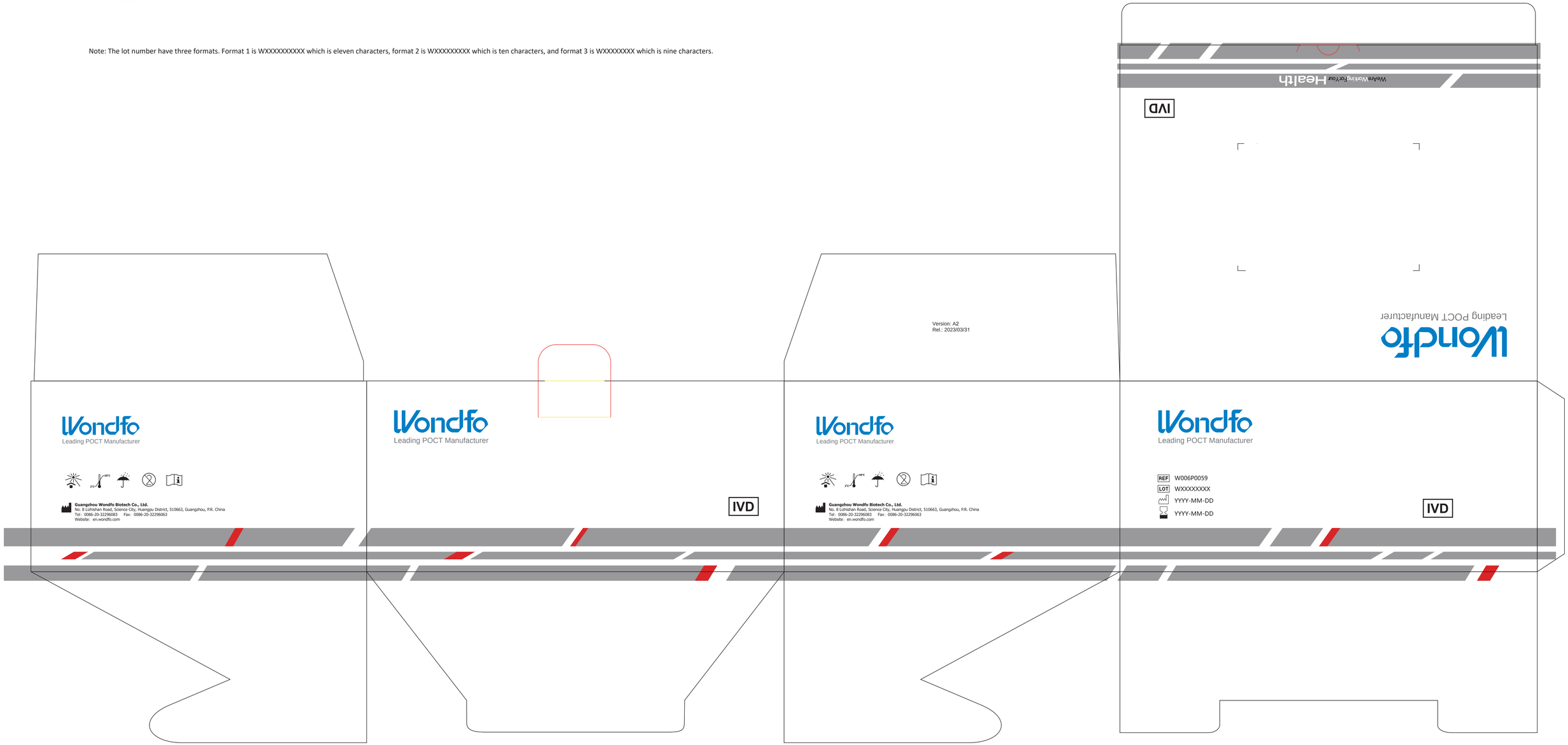


Round Sticker

1.2 Labels for product code W006P0059

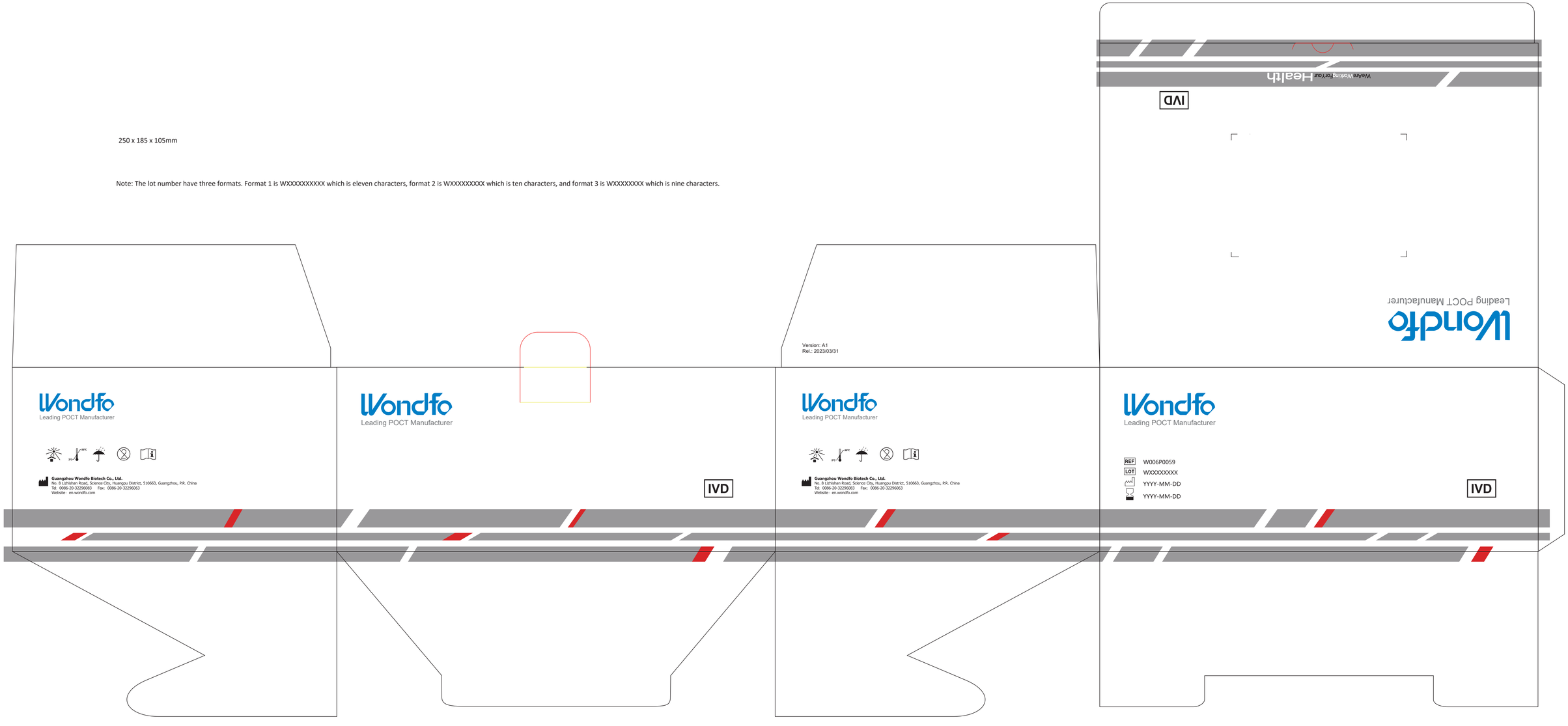
230 x185x 105 mm

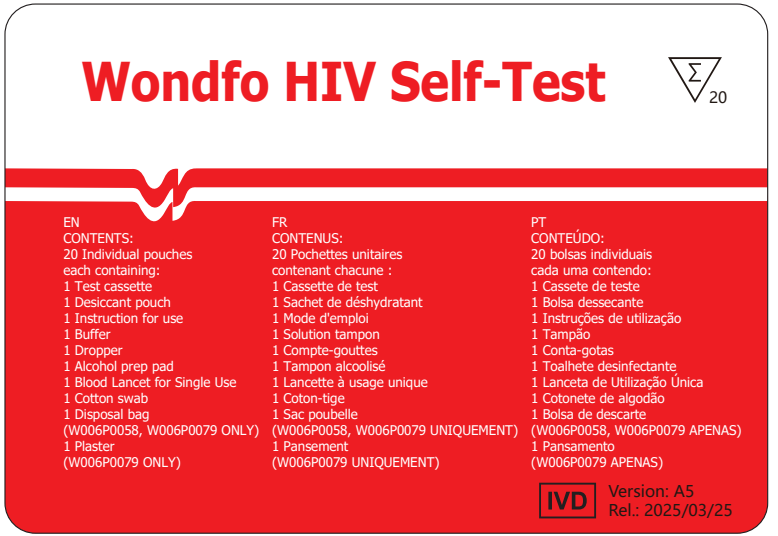
Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.



250 x 185 x 105mm

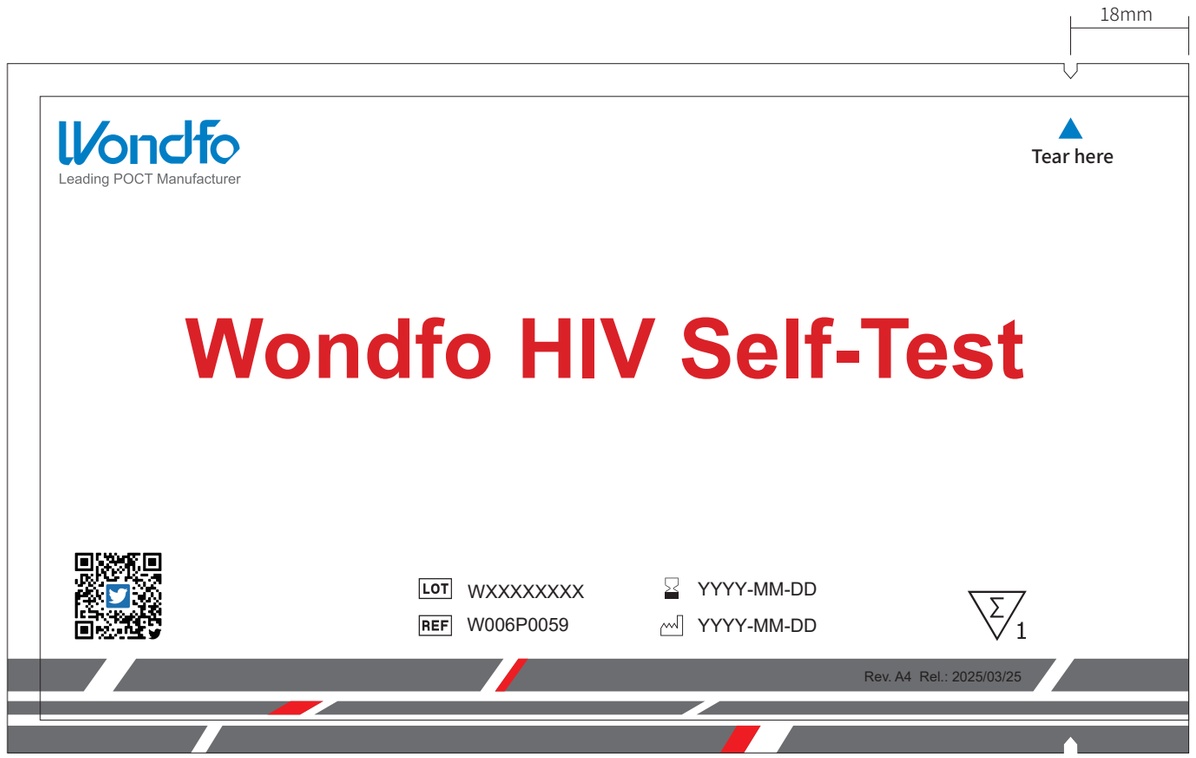
Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.



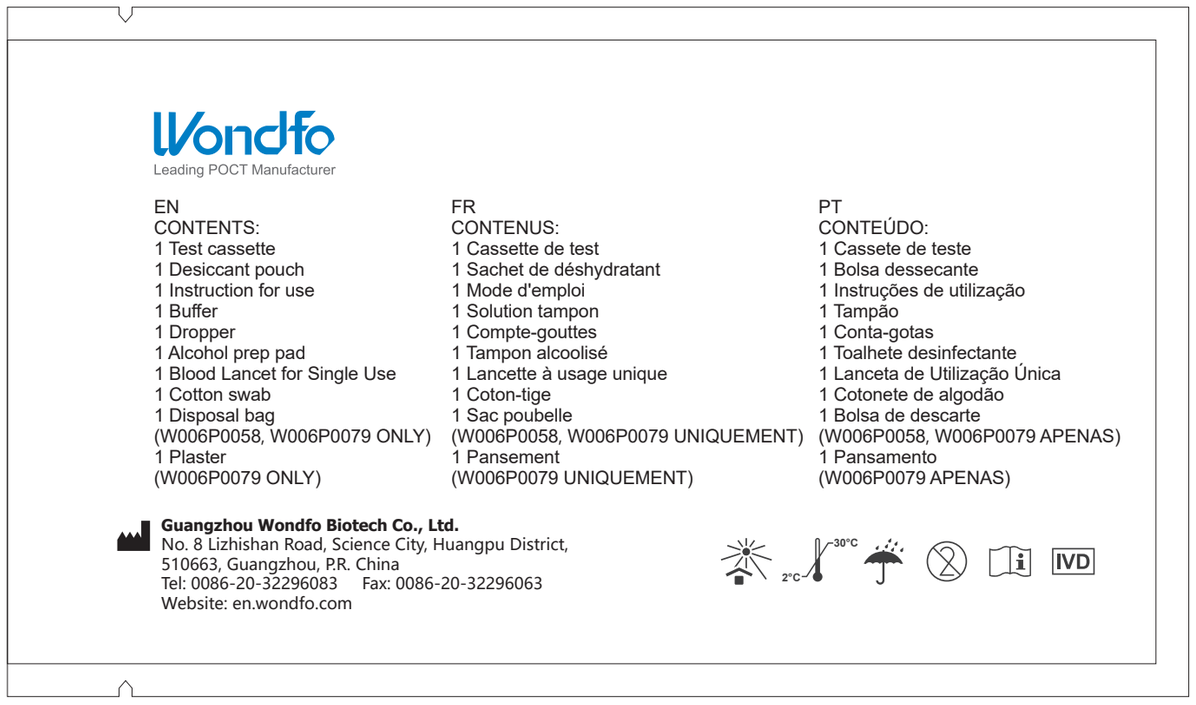


Secondary Packaging Label of W006P0059

Front



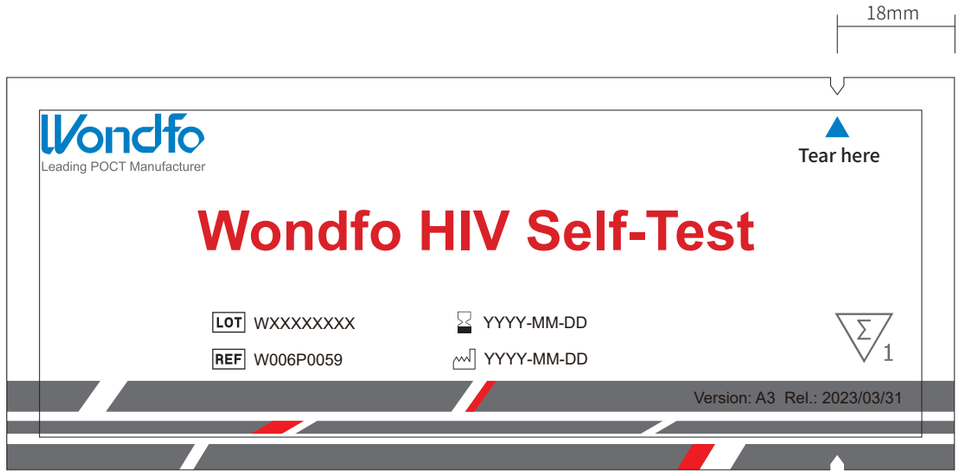
Back



Foil Pouch for W006P0059

Note: The lot number have three formats. Format 1 is WXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXX which is ten characters, and format 3 is WXXXXXXX which is nine characters.

Front



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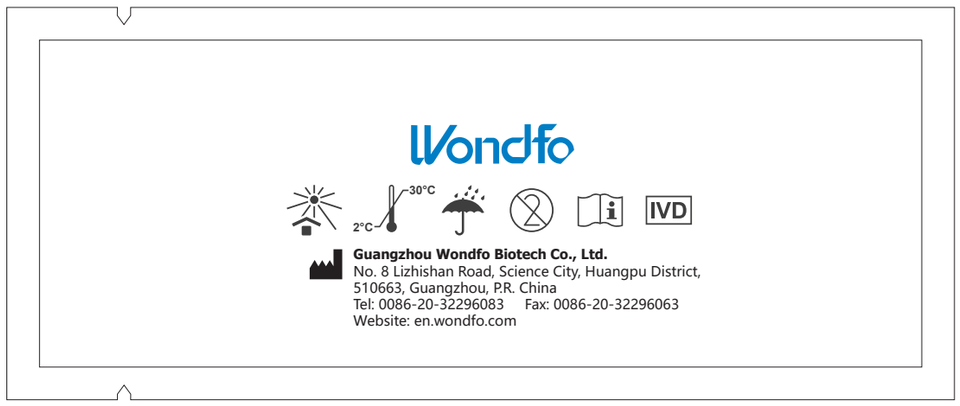
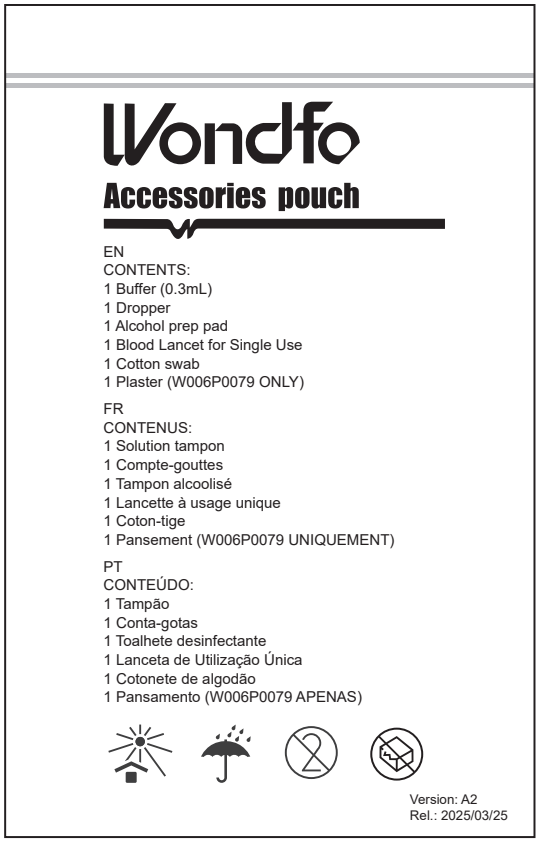


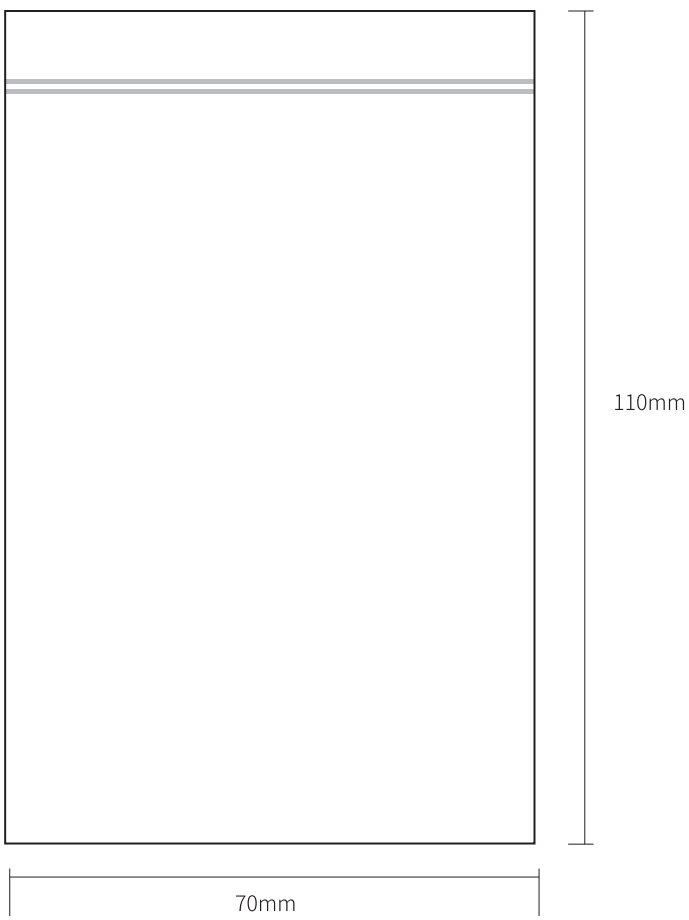
Test Cassette Foil Pouch for W006P0059

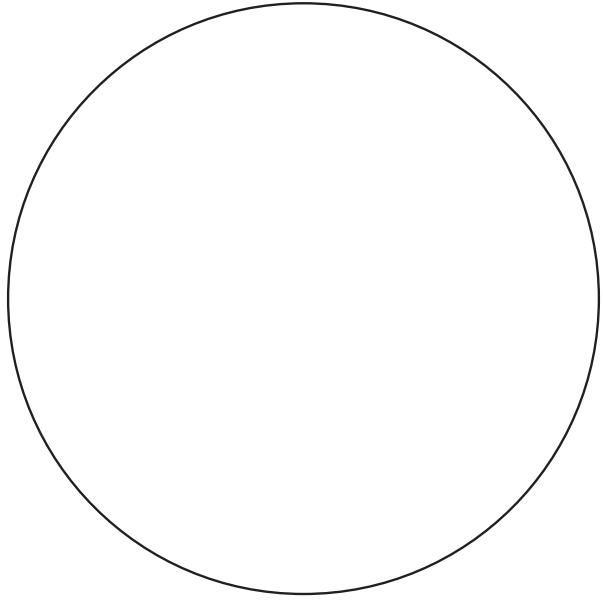
Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.

Front


10mm
Wondfo
Accessories pouch
EN
CONTENTS:
1 Buffer (0.3mL)
1 Dropper
1 Alcohol prep pad
1 Blood Lancet for Single Use
1 Cotton swab
1 Plaster (W006P0079 ONLY)
FR
CONTENUS:
1 Solution tampon
1 Compte-gouttes
1 Tampon alcoolisé
1 Lancette à usage unique
1 Coton-tige
1 Pansement (W006P0079 UNIQUEMENT)
PT
CONTEÚDO:
1 Tampão
1 Conta-gotas
1 Toalhete desinfectante
1 Lanceta de Utilização Única
1 Cotonete de algodão
1 Pansamento (W006P0079 APENAS)
Version: A2
Rel.: 2025/03/25

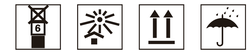
Back


110mm
70mm



Round Sticker

1.3 Labels for product code W006P0060

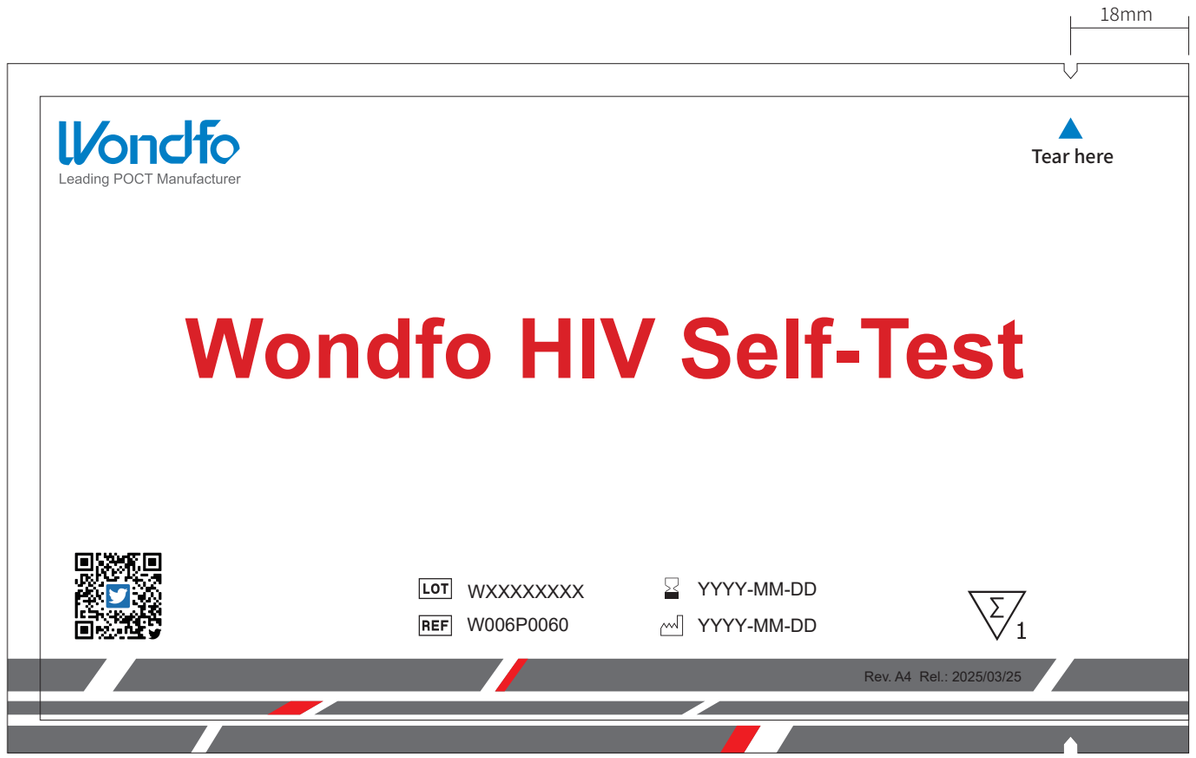
	 ART NO.: C/NO.: QTY: PCS N.W: KGS G.W: KGS MEAS: 36×28×21 CM		 ART NO.: C/NO.: QTY: PCS N.W: KGS G.W: KGS MEAS: 36×28×21 CM

Secondary packaging of W006P0060

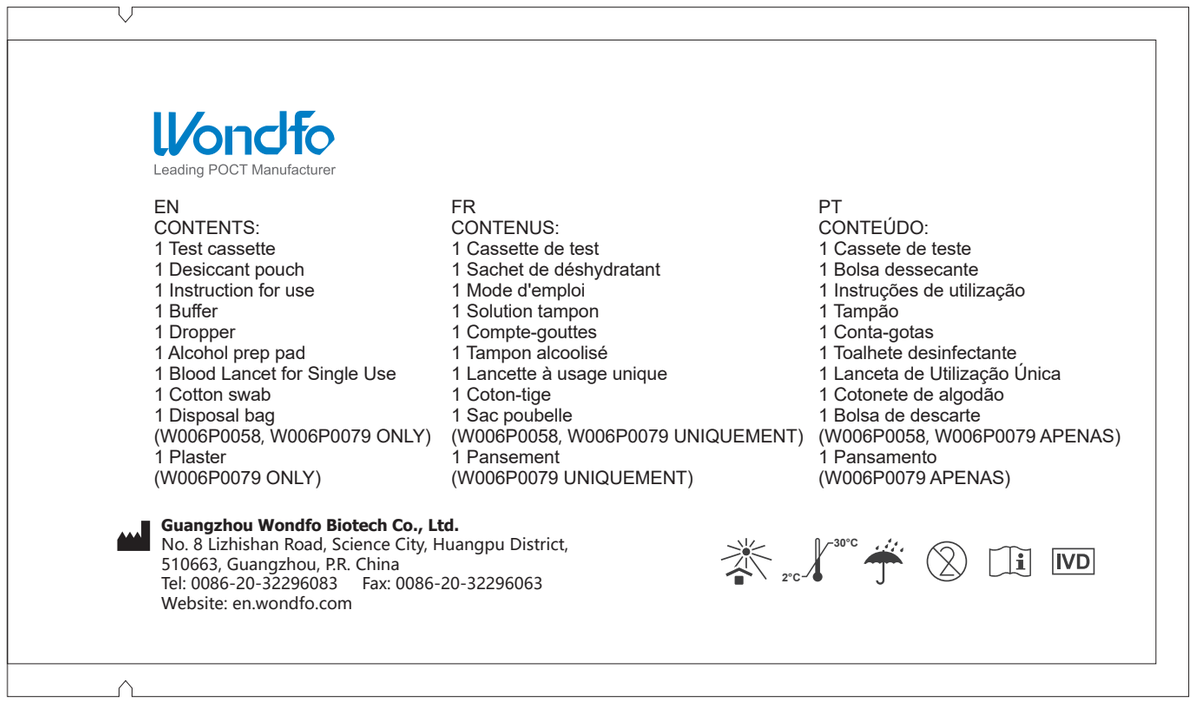
Secondary Packaging Label for W006P0060

Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.

Front



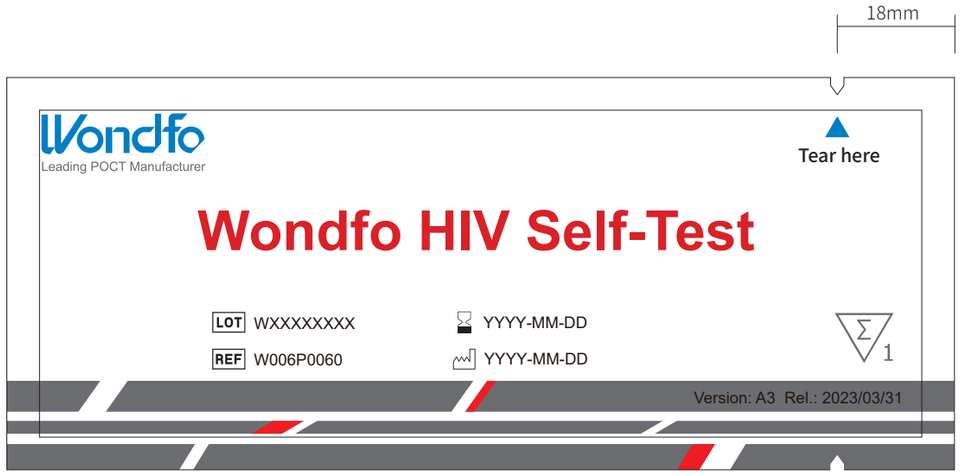
Back



Foil Pouch for W006P0060

Note: The lot number have three formats. Format 1 is WXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXX which is ten characters, and format 3 is WXXXXXXX which is nine characters.

Front



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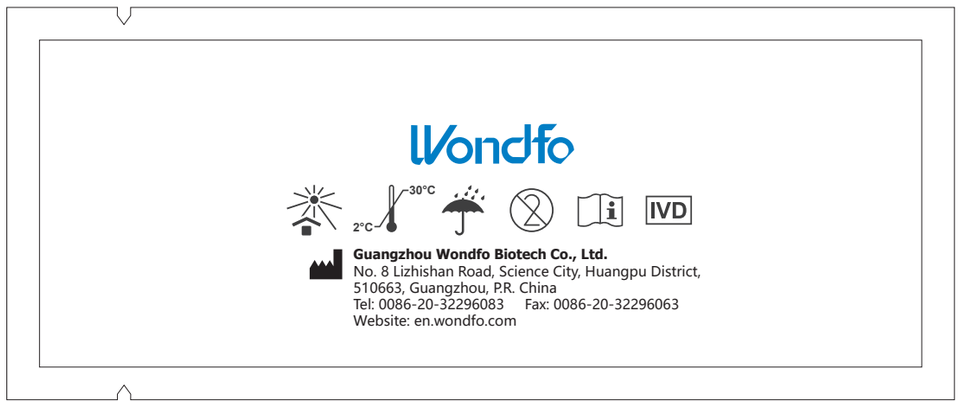
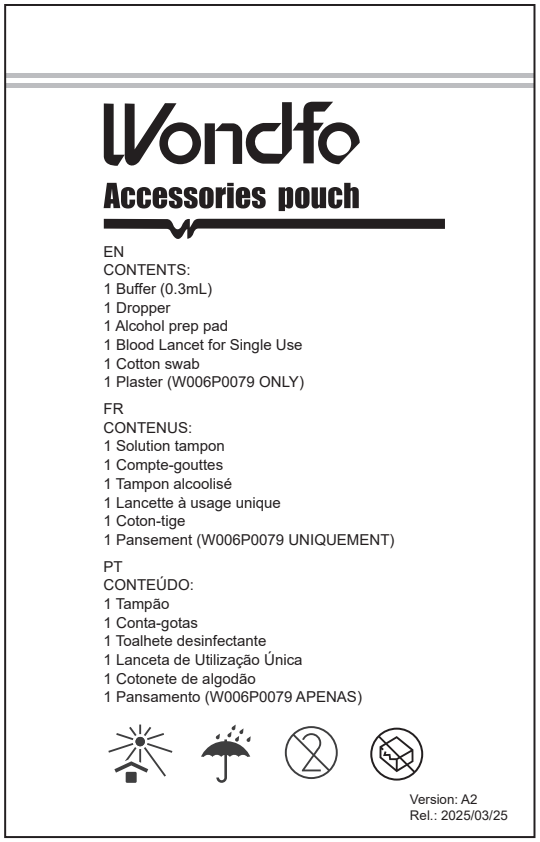


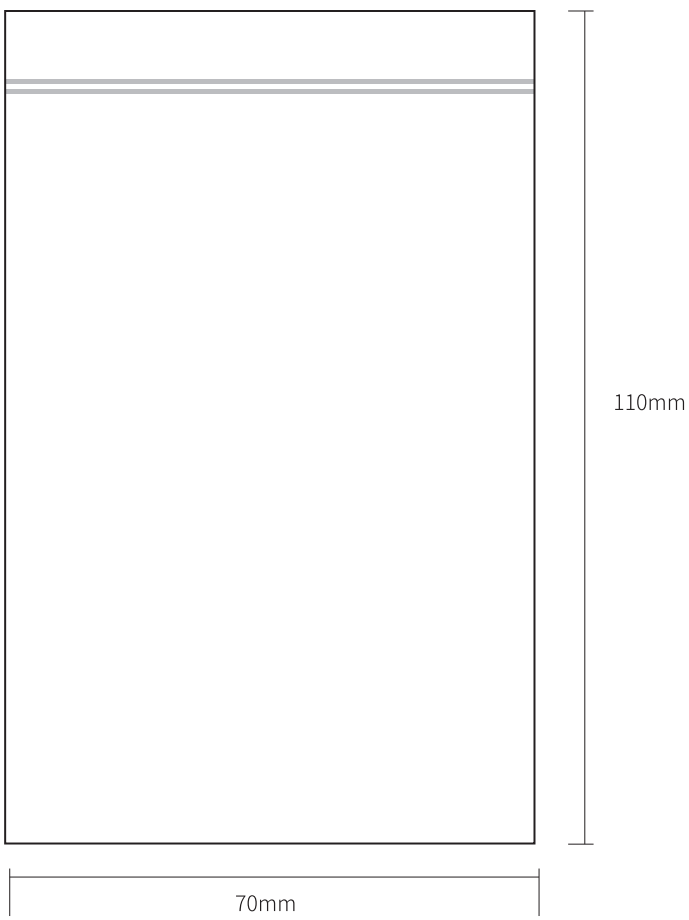
Test Cassette Foil Pouch for W006P0060

Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.

Front


10mm
Wondfo
Accessories pouch
EN
CONTENTS:
1 Buffer (0.3mL)
1 Dropper
1 Alcohol prep pad
1 Blood Lancet for Single Use
1 Cotton swab
1 Plaster (W006P0079 ONLY)
FR
CONTENUS:
1 Solution tampon
1 Compte-gouttes
1 Tampon alcoolisé
1 Lancette à usage unique
1 Coton-tige
1 Pansement (W006P0079 UNIQUEMENT)
PT
CONTEÚDO:
1 Tampão
1 Conta-gotas
1 Toalhete desinfectante
1 Lanceta de Utilização Única
1 Cotonete de algodão
1 Pansamento (W006P0079 APENAS)
Version: A2
Rel.: 2025/03/25

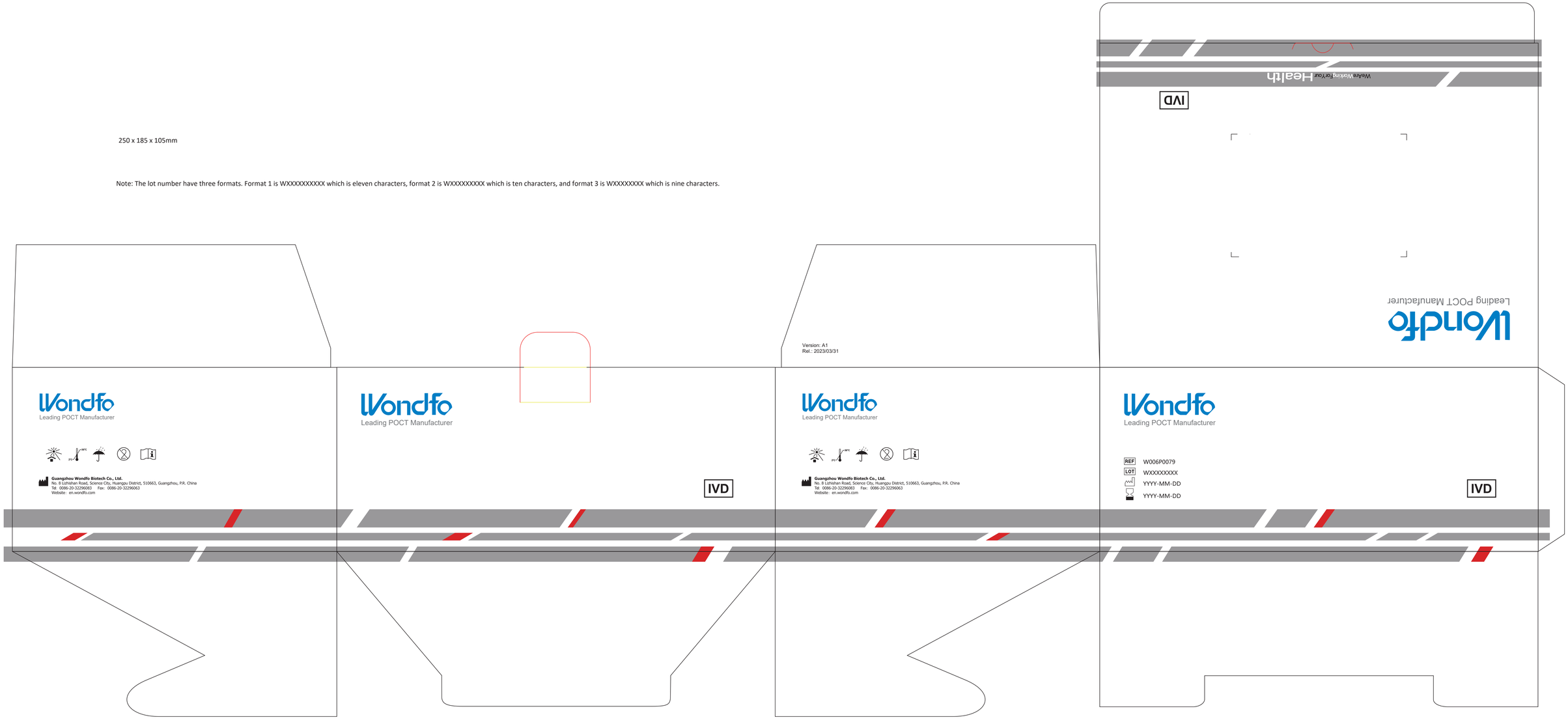
Back

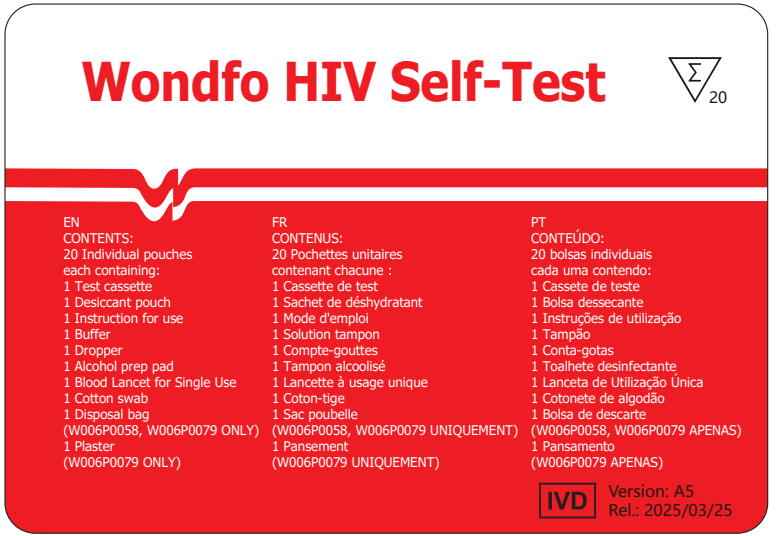

110mm
70mm

1.4 Labels for product code W006P0079

250 x 185 x 105mm

Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.





Secondary Packaging Label of W006P0079

Front

18mm

Wondfo
Leading POCT Manufacturer

Tear here

Wondfo HIV Self-Test

LOT WXXXXXXXX
REF W006P0079

YYYY-MM-DD
YYYY-MM-DD

Σ 1

Rev. A4 Rel.: 2025/03/25

Back

Wondfo
Leading POCT Manufacturer

EN
CONTENTS:
1 Test cassette
1 Desiccant pouch
1 Instruction for use
1 Buffer
1 Dropper
1 Alcohol prep pad
1 Blood Lancet for Single Use
1 Cotton swab
1 Disposal bag
(W006P0058, W006P0079 ONLY)
1 Plaster
(W006P0079 ONLY)

FR
CONTENUS:
1 Cassette de test
1 Sachet de déshydratant
1 Mode d'emploi
1 Solution tampon
1 Compte-gouttes
1 Tampon alcoolisé
1 Lancette à usage unique
1 Coton-tige
1 Sac poubelle
(W006P0058, W006P0079 UNIQUEMENT)
1 Pansement
(W006P0079 UNIQUEMENT)

PT
CONTEÚDO:
1 Cassete de teste
1 Bolsa dessecante
1 Instruções de utilização
1 Tampão
1 Conta-gotas
1 Toalhete desinfectante
1 Lanceta de Utilização Única
1 Cotonete de algodão
1 Bolsa de descarte
(W006P0058, W006P0079 APENAS)
1 Pansamento
(W006P0079 APENAS)

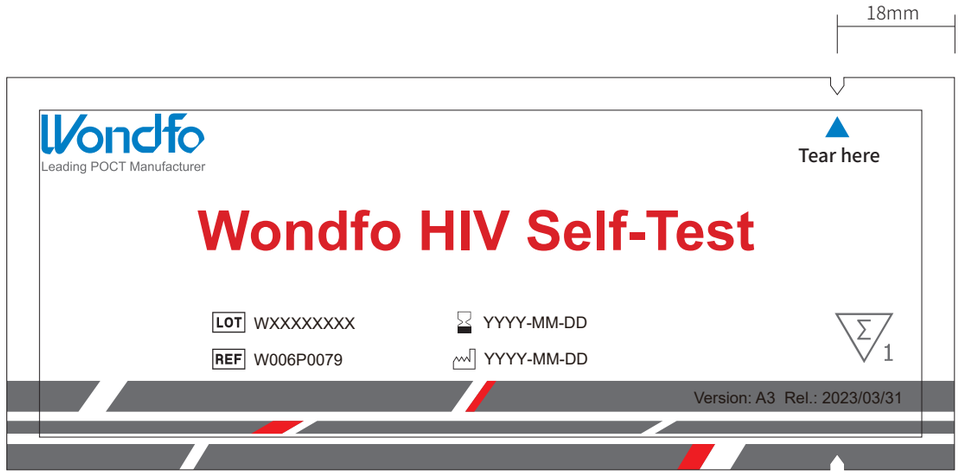
Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Huangpu District,
510663, Guangzhou, P.R. China
Tel: 0086-20-32296083 Fax: 0086-20-32296063
Website: en.wondfo.com

2°C 30°C IVD

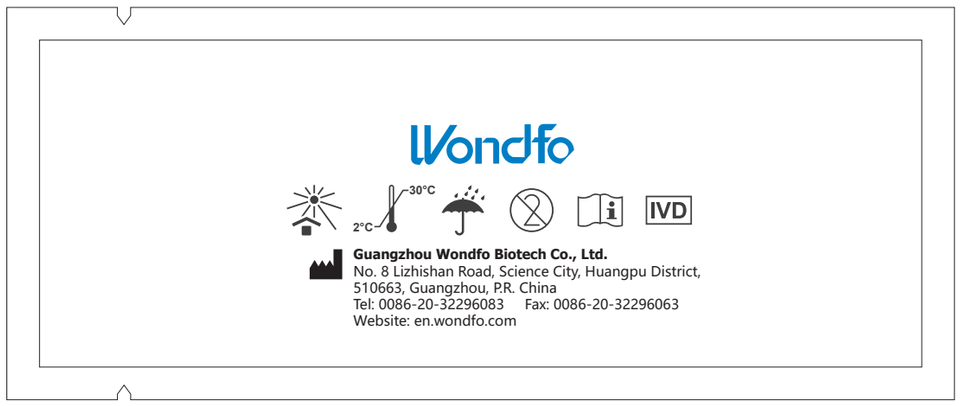
Foil Pouch for W006P0079

Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.

Front



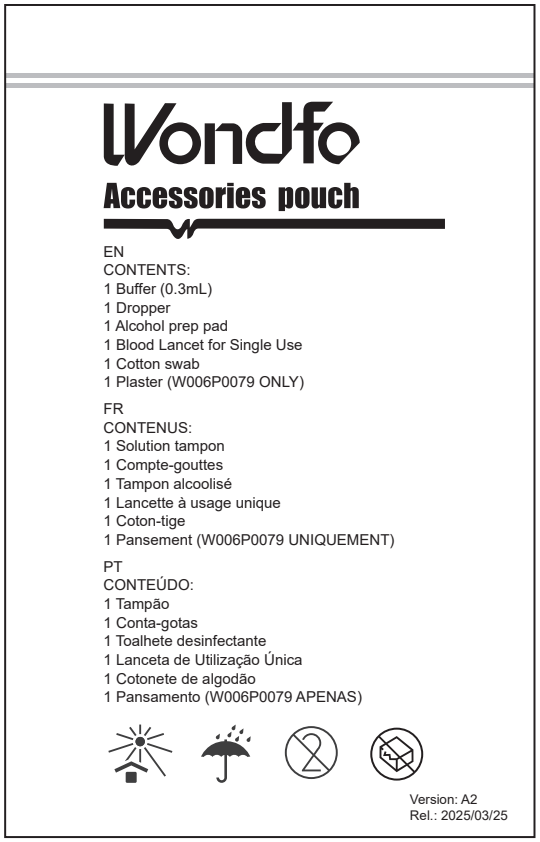
Back



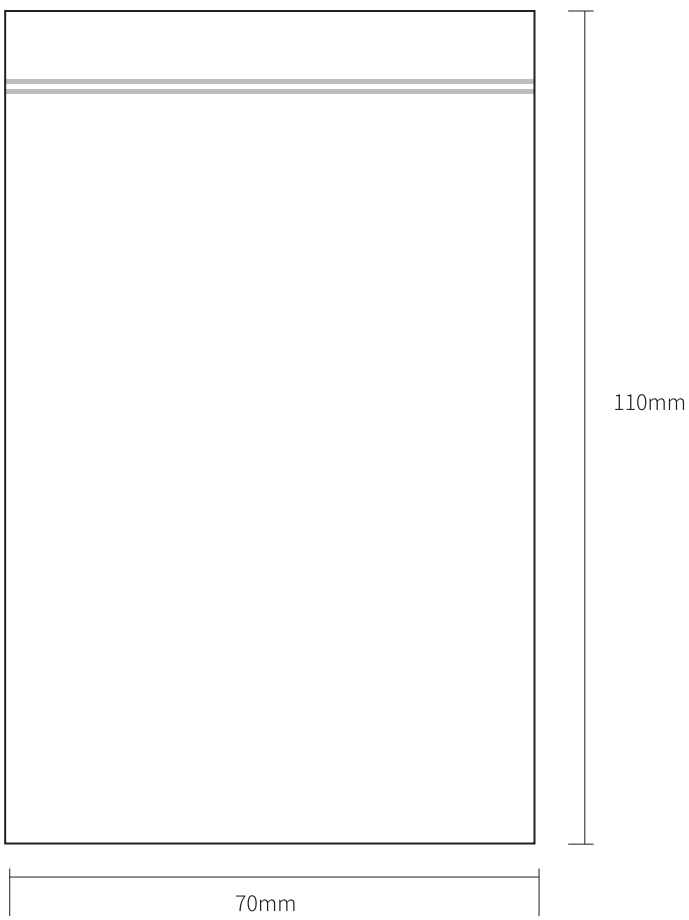
Test Cassette Foil Pouch for W006P0079

Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.

Front


10mm
Wondfo
Accessories pouch
EN
CONTENTS:
1 Buffer (0.3mL)
1 Dropper
1 Alcohol prep pad
1 Blood Lancet for Single Use
1 Cotton swab
1 Plaster (W006P0079 ONLY)
FR
CONTENUS:
1 Solution tampon
1 Compte-gouttes
1 Tampon alcoolisé
1 Lancette à usage unique
1 Coton-tige
1 Pansement (W006P0079 UNIQUEMENT)
PT
CONTEÚDO:
1 Tampão
1 Conta-gotas
1 Toalhete desinfectante
1 Lanceta de Utilização Única
1 Cotonete de algodão
1 Pansamento (W006P0079 APENAS)
Version: A2
Rel.: 2025/03/25

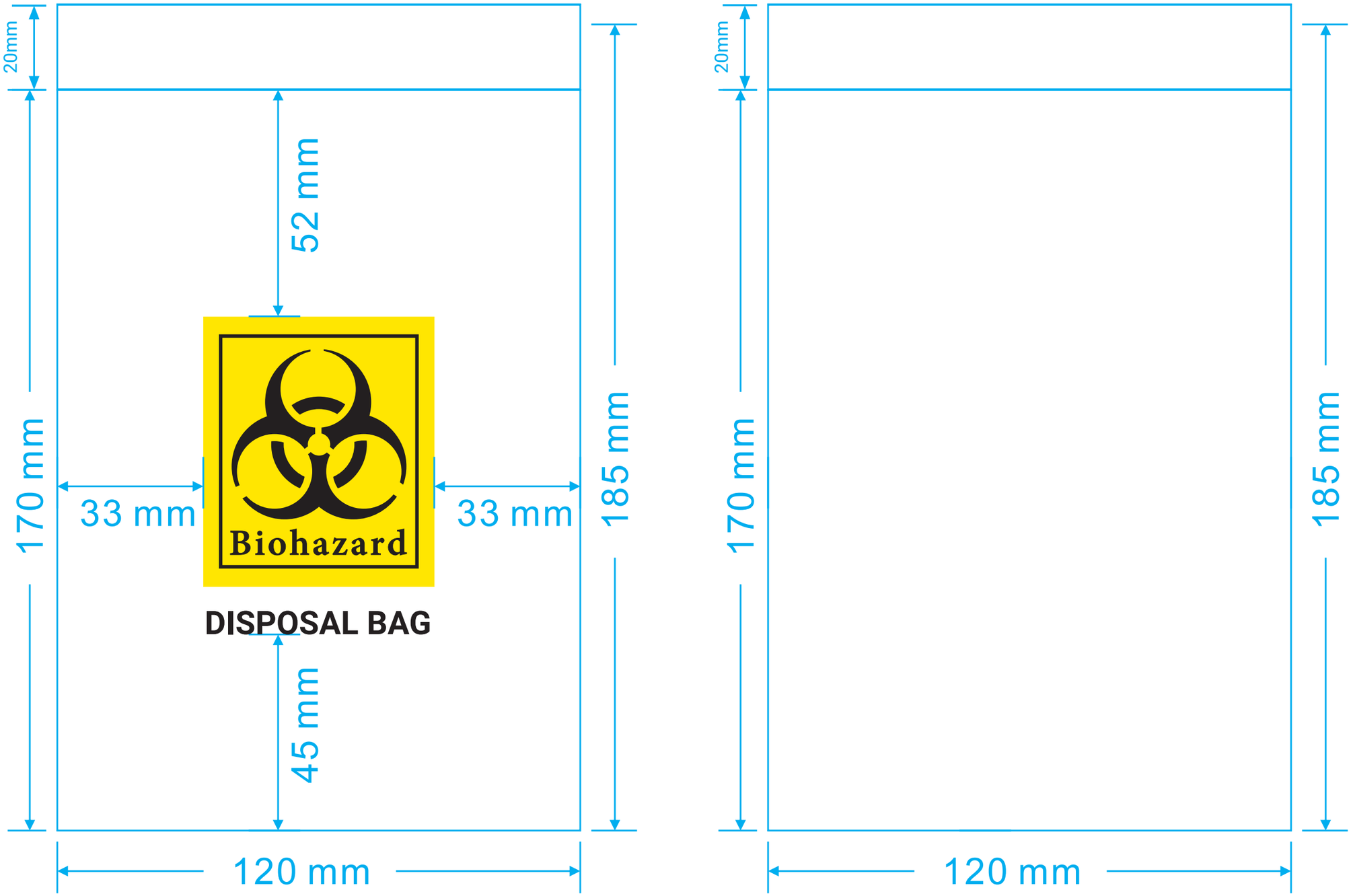
Back


110mm
70mm

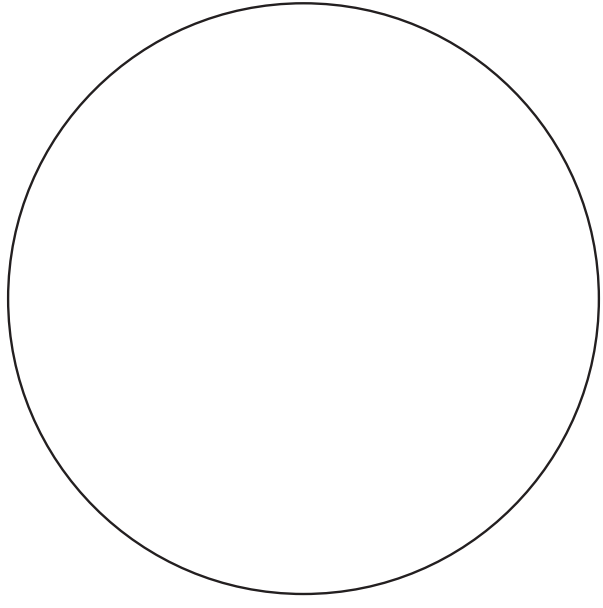
Sterile Wound Plaster

CE 0123

STERILE EO



Disposable Bag for W006P0079



Round Sticker

Instructions for use[4]

[4] 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.

ENGLISH

Rev. A8 Rel.: 2025/05/28

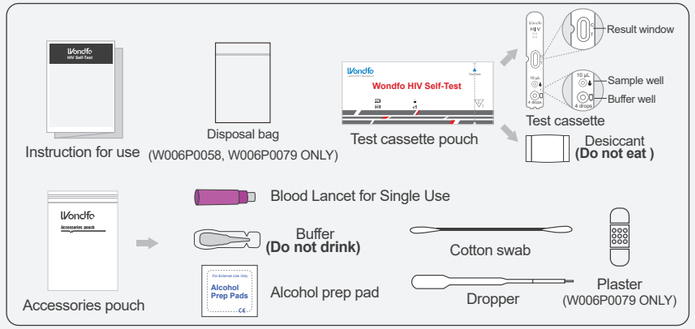
Wondfo HIV Self-Test

Instruction for use

- You must follow the test procedure carefully to get an accurate result.
- Sit in a clean, well-lit area and ensure you have all contents before beginning the test.
- For single-use only. Do not open foil pouch containing cassette until ready to test.

Watch the operation video

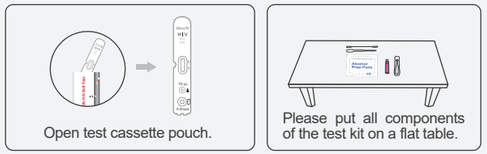
Contents



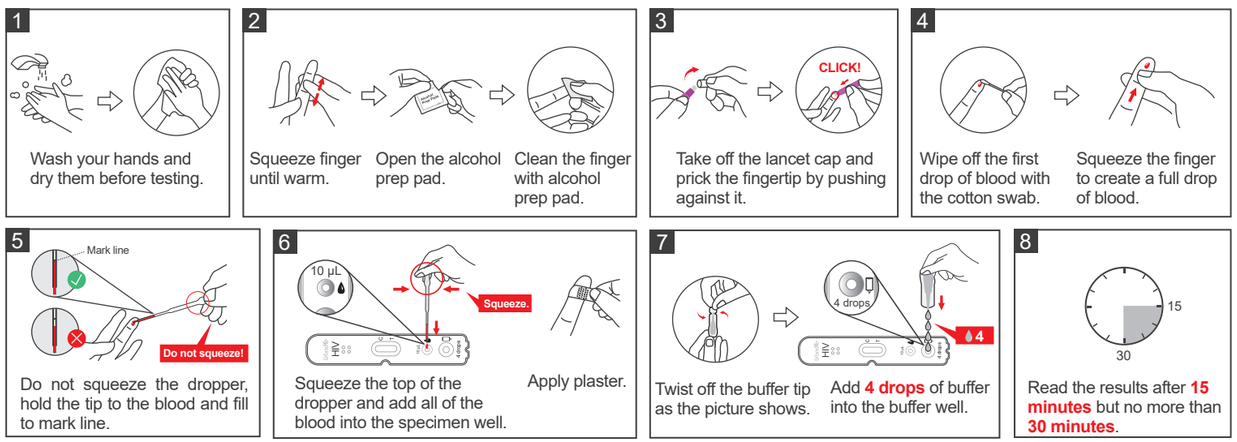
Materials may be required but not provided.

Timer Tissue

Preparation



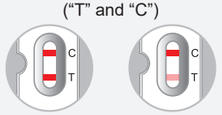
How to use the test kit (for fingerstick whole blood use)



How to read the test

Positive (+)

Presence of two color bands ("T" and "C")



Go to a clinic for confirmatory testing as soon as possible.

Negative (-)

No presence of color band ("T")

Test again in 3 months if recently exposed to HIV or if at high risk of infection. Ask about HIV prevention services at the nearest clinic.

Invalid

No presence of color band ("C")

Run another test or go to a clinic for confirmatory testing.

DISPOSE

Throw away all contents in the normal trash or dispose according to local infectious waste disposal laws and regulations.

Questions and answers

1. What is HIV?

The human immunodeficiency virus (HIV) targets cells of the immune system, called CD4 cells, which help the body respond to infection. Within the CD4 cell, HIV replicates and in turn, damages and destroys the cell. Without effective treatment of a combination of antiretroviral (ARV) drugs, the immune system will become weakened to the point that it can no longer fight infection and disease.

2. How is HIV transmitted?

HIV is found in certain bodily fluids of people living with HIV, including blood, semen, vaginal fluids, rectal fluids and breastmilk. HIV can be transmitted by:

- Unprotected vaginal or anal sex, and, in very rare cases, through oral sex with a person living with HIV.
- Blood transfusion of contaminated blood.
- Sharing of needles, syringes, other injecting equipment, surgical equipment or other sharp instru ments.
- From a mother living with HIV to her infant during pregnancy, childbirth or breastfeeding.

If a person living with HIV is on ART (Antiretroviral therapy), which effectively suppresses HIV in the body, their chance of transmitting HIV to another person is greatly reduced.

3. When do I need to test myself?

People who have been exposed to HIV or are at risk of HIV should seek testing. Most widely-used HIV diagnostic tests detect antibodies produced by the person as part of their immune response to fight HIV. In most cases, people develop antibodies to HIV within 28 days of infection. During this time, people may receive a false-negative result using an antibody test. While people at risk of HIV should test as soon as possible, negative test results within 28 days of exposure should be confirmed with additional testing no more than three months later.

4. What should I do if I get a positive result?

You need to follow up with a health care worker to get additional testing to confirm the result. At that time your local clinic and the provider will suggest the next steps that need to be taken.

Product information

CATALOG NO.

W006P0058 W006P0059 W006P0060 W006P0079

INTENDED USE

The Wondfo HIV Self-Test is a single-use *in vitro* diagnostic self-test for fingerstick whole blood detection of HIV-1/2. It is intended to be used as self-test and/or by medical professionals.

For *in vitro* diagnostic use only.

PRINCIPLES OF THE PROCEDURE

Wondfo HIV Self-Test adopts double antigen sandwich immunochromatography method. Once the specimen and the buffer are added into the respective wells, they will migrate along the device by capillary action. The HIV-1 and/or HIV-2 antibodies bind to the colloidal gold-HIV antigen (gp36/41), and the complex is then captured by the HIV recombinant antigen (gp41 and gp36) immobilized in the test region (T). When the levels of HIV-1 or HIV-2 antibodies are at or above the limit of detection (LOD) of the assay, it will produce a visible colored band in the test region (T) and indicates a positive result. When the levels of HIV-1 or HIV-2 antibodies are zero or below the LOD, there is no visible colored band in the test region (T) indicating a negative result. To serve as an internal procedure control, a colored line will appear at the control region (C).

WARNINGS AND CAUTIONS

Do not use if the test kit beyond expiration date.
Do not use if the pouch is punctured or improperly sealed.
Do not use for self-testing if you are under 12 years old.
Do not use for self-testing if you have a bleeding disorder.
Do not use for self-testing if you are already diagnosed as HIV positive.
Do not open the pouch until you are ready to perform the test.
Wash your hands and ensure that they are clean and dry before starting test.
Adequate lighting is required to read the test results.

KIT CONTENT

There are 4 configurations of the test kits, 1 test/kit, 20 tests/kit and 100 tests/kit.
The kit components are provided as below:

Components \ Catalog No.		W006P0058	W006P0059	W006P0060	W006P0079
Test cassette pouch	Test cassette (pcs)	1	1x20	1x100	1x20
	Desiccant (pcs)	1	1x20	1x100	1x20
Accessories	Dropper (pcs)	1	1x20	1x100	1x20
	Buffer (vial)	1	1x20	1x100	1x20
	IFU (pcs)	1	1x20	1x100	1x20
	Blood Lancet for Single Use (pcs)	1	1x20	1x100	1x20
	Alcohol prep pad (pcs)	1	1x20	1x100	1x20
	Cotton swab (pcs)	1	1x20	1x100	1x20
	Disposal bag (pcs)	1	/	/	1x20
	Plaster (pcs)	/	/	/	1x20

One test strip includes: Gold conjugate (HIV gp41/gp36 fusion recombinant antigen-gold colloid and rabbit IgG polyclonal antibody-gold colloid), Test line (HIV gp41 recombinant antigen and HIV gp36 recombinant antigen) and Control line (Goat anti rabbit IgG polyclonal antibody).

STORAGE AND STABILITY

1. The test kit can be stored at 2-30 °C until the stated Expiry Date on the kit.
2. Use the test cassette within 1 hour after opening the pouch.
3. Keep away from sunlight, moisture and heat.
4. Use the kit at 10-30 °C.

LIMITATIONS OF THE PROCEDURE

1. The test is designed for testing human fingerstick whole blood.
2. The test is limited to the qualitative detection of HIV-1 and HIV-2 antibodies.
3. The assay procedure and result interpretation must be followed closely when testing. For optimal test performance, proper specimen collection is critical. Failure to follow the procedure may lead to inaccurate test results.
4. False-negative results can occur in the following conditions:
   - Patients exposed to HIV less than 3 months.
   - Patients under HIV treatment (Antiretroviral therapy).
   - If the quantity of antibodies for HIV present in the specimen is below the detection limit of the assay.
5. False-positive results can occur in the following conditions:
   - Patients have participated in a HIV vaccine clinical trial.
6. 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.
7. 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 healthcare provider in conjunction with clinical findings and the results from other laboratory tests and evaluations. Results from the Wondfo HIV Self-Test should not be used as the sole basis for diagnosis.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity:

A clinical study of the Wondfo HIV Self-Test was conducted in 5 different test institutions. Healthcare professionals tested 3911 samples with the Wondfo HIV Self-Test. Laboratory testing confirmed that 1172 samples were HIV positive and 2739 were HIV negative.

- Sensitivity: 100% (95%CI: 99.67% - 100%) - the Wondfo HIV Self-Test correctly identified all 1172 HIV positive samples.
- Specificity: 99.96% (95%CI: 99.79% - 99.99%) - the Wondfo HIV Self-Test correctly identified 2738 of the 2739 HIV negative samples.

Usability Study:

A usability study was conducted in which 900 untrained lay participants whose HIV status was previously unknown tested themselves using the Wondfo HIV Self-Test. The participants' HIV true status was determined by testing with a 4th generation (HIV Ag/Ab) laboratory test.

- 42 (4.7%) of the 900 participating lay-users, failed to obtain a Self-Test result, including 5 whose laboratory test was HIV positive. An additional participant's 4th generation HIV test status was not determined before the study closed.
- 69 (95.8%) of the remaining 72 laboratory confirmed HIV positive lay-users correctly reported a positive Self-Test.
- 782 (99.6%) of the remaining 785 laboratory confirmed HIV negative lay-users correctly reported a negative Self-Test.

REFERENCES

1. WHO. TGS-5 Designing instruction for use for *in vitro* diagnostic medical devices, Geneva: World Health Organization; 2019.
2. Medicines and Healthcare products Regulatory Agency. Guidance for notified bodies on the regulation of IVDs for self-testing. London, U.K.: MHRA, Competent Authority (UK); 2012.
3. WHO. TSS-1 Human Immunodeficiency Virus(HIV) rapid diagnostic tests for professional use and/or selftesting, Geneva: World Health Organization; 2016.

SYMBOLS KEY

IVD — *In vitro* diagnostic medical device	Consult instructions for use	Use-by date
Contains sufficient for <n> tests	Date of manufacture	Keep dry
LOT — Batch code	Temperature limit	Keep away from sunlight
Manufacturer	Do not re-use	REF — Catalogue number
Caution	Do not use if package is damaged and consult *instructions for use*	

Manufacturer information

Guangzhou Wondfo Biotech Co., Ltd.

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Tel: +86-20-32296083 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 related to the product.

FRANÇAIS

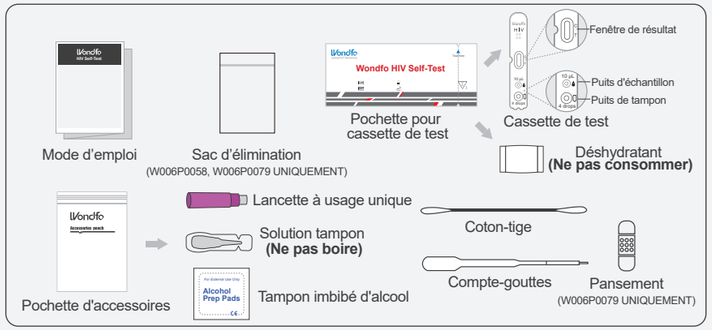
Wondfo HIV Self-Test

Mode d'emploi

- Vous devez suivre attentivement la procédure de test pour obtenir un résultat précis.
- Asseyez-vous dans un endroit propre et bien éclairé et assurez-vous d'avoir tout le contenu avant de commencer le test.
- À usage unique. N'ouvrez pas la pochette en aluminium contenant la cassette avant d'être prêt à effectuer le test.

Regardez la vidéo de l'opération

Contenu

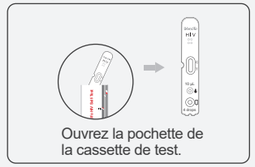


Matériel pourrait être requis mais non fourni.

Minuterie

Serviettes en papier

Préparation



Ouvrez la pochette de la cassette de test.

Veuillez placer tous les composants du kit de test sur une table plate.

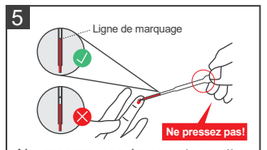
Comment utiliser le kit de test (pour le sang total prélevé sur un doigt)

1. Lavez vos mains et séchez-les avant de procéder au test.

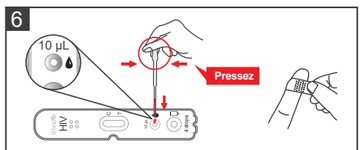
2. Pressez le doigt jusqu'à ce qu'il soit chaud. Ouvrez le tampon imbibé d'alcool. Nettoyez le doigt avec le tampon imbibé d'alcool.

3. Retirez le capuchon de la lancette jetable et piquez le bout du doigt en appuyant dessus.

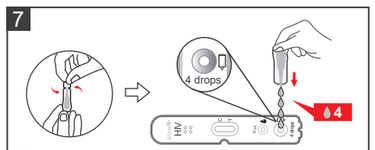
4. Essuyez la première goutte de sang avec un coton-tige. Pressez le doigt pour avoir une goutte de sang suffisante.



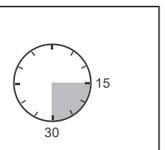
5. Ne pressez pas le compte-gouttes, dirigez l'extrémité du compte-gouttes vers le sang et remplissez-le jusqu'à la ligne de marquage.



6. Pressez la partie supérieure du compte-gouttes et ajoutez tout le sang dans le puits d'échantillon. Appliquer un pansement.



7. Enlevez l'embout de la solution tampon comme indiqué sur l'image. Ajoutez **4 gouttes** de Solution tampon dans le puits de tampon.

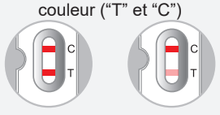


8. Lisez le résultat après **15 minutes** mais pas plus de **30 minutes**.

Comment lire le test

Positif (+)

Présence de deux bandes de couleur ("T" et "C")



Rendez-vous dans un centre de santépour un test de confirmation dès que possible.

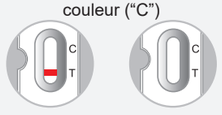
Négatif (-)

Pas de présence de bande de couleur ("T")

Refaites le test dans 3 mois si vous avez été récemment exposé au VIH ou si vous présentez un risque élevé d'infection. Renseignez-vous sur les services de prévention du VIH dans le centre de santé le plus proche.

Invalide

Pas de présence de la bande de couleur ("C")



Effectuez un autre test ou allez dans un cetre de santé pour un test de confirmation.

Élimination

Jetez tous les objets contenus dans la poubelle ordinaire ou l'éliminez conformément aux lois et règlements locaux en matière d'élimination des déchets infectieux.

Questions et réponses

1. Qu'est-ce que le VIH ?

Le virus de l'immunodéficience humaine (VIH) cible les cellules du système immunitaire, appelées cellules CD4, qui aident l'organisme à réagir aux infections. À l'intérieur de la cellule CD4, le VIH se réplique et, à son tour, endommage et détruit la cellule. Sans traitement efficace par une combinaison de médicaments antirétroviraux (ARV), le système immunitaire s'affaiblit au point de ne plus pouvoir lutter contre les infections et les maladies.

2. Comment le VIH se transmet-il ?

Le VIH se trouve dans certains fluides corporels des personnes vivant avec le VIH, notamment le sang, le sperme, les fluides vaginaux, les fluides rectaux et le lait maternel. Le VIH peut être transmis par :

- Des rapports sexuels vaginaux ou anaux non protégés, et dans de très rares cas, par des rapports sexuels oraux avec une personne vivant avec le VIH.
- La transfusion de sang contaminé.
- Le partage d'aiguilles, de seringues, d'autres matériels d'injection, de matériel chirurgical ou d'autres instruments tranchants.
- D'une mère vivant avec le VIH à son enfant pendant la grossesse, l'accouchement ou l'allaitement.

Si une personne vivant avec le VIH suit un traitement ART (thérapie antirétrovirale), qui supprime efficacement le VIH dans l'organisme, le risque de transmission du VIH à une autre personne est considérablement réduit.

3. Quand dois-je me faire tester ?

Les personnes qui ont été exposées au VIH ou qui sont à risque de contracter le VIH doivent se faire tester. La plupart des tests de diagnostic du VIH couramment utilisés détectent les anticorps produits par la personne dans le cadre de sa réponse immunitaire pour combattre le VIH. Dans la plupart des cas, les personnes développent des anticorps contre le VIH dans les 28 jours suivant l'infection. Pendant cette période, les personnes peuvent recevoir un résultat faussement négatif en utilisant un test d'anticorps. Bien que les personnes à risque d'infection par le VIH doivent être testées dès que possible, les résultats négatifs obtenus dans les 28 jours suivant l'exposition doivent être confirmés par un test supplémentaire au plus tard trois mois plus tard.

4. Que dois-je faire si le résultat est positif ?

Vous devez faire un suivi auprès d'un professionnel de la santé pour effectuer des tests supplémentaires afin de confirmer le résultat. À ce moment-là, votre clinique locale et le prestataire vous suggéreront des prochaines étapes à suivre.

Informations sur les produits

N° DE CATALOGUE

W006P0058 W006P0059 W006P0060 W006P0079

UTILISATION PRÉVUE

Wondfo HIV Self-Test est un autotest de diagnostic *in vitro* à usage unique pour le dépistage du VIH-1/2 dans le sang total prélevé au bout du doigt. Il est destiné à être utilisé comme autotest et/ou par des professionnels de la santé.

Uniquement pour l'usage diagnostique *in vitro*.

PRINCIPES DE LA PROCÉDURE

Wondfo HIV Self-Test adopte la méthode sandwich à double antigène. Une fois que l'échantillon et la solution tampon sont ajoutés dans leurs puits respectifs, ils vont migrer le long du dispositif par action capillaire. Les anticorps du VIH-1 et/ou du VIH-2 se lient à l'antigène du VIH en or colloïdal (gp36/41), et le complexe est ensuite capturé par l'antigène recombinant du VIH (gp41 et gp36) immobilisé dans la région de test (T). Lorsque les niveaux d'anticorps anti-VIH-1 ou anti-VIH-2 sont égaux ou supérieurs à la limite de détection (LD) du test, celui-ci produit une bande colorée visible dans la zone de test (T) et indique un résultat positif. Lorsque les niveaux d'anticorps anti-VIH-1 ou anti-VIH-2 sont nuls ou inférieurs à la LD, il n'y a pas de bande colorée visible dans la région de test (T), ce qui indique un résultat négatif. Pour servir de contrôle interne de la procédure, une ligne colorée apparaîtra dans la région de contrôle (C).

AVERTISSEMENTS ET ATTENTIONS

N' utilisez pas si le kit de test a dépassé la date de péremption.
N' utilisez pas si la pochette est perforée ou mal scellée.
N' utilisez pas pour l'auto-test si vous avez moins de 12 ans.
N' utilisez pas pour l'auto-test si vous avez un trouble de la coagulation.
N' utilisez pas pour l'auto-test si vous êtes déjà diagnostiqué séropositif.
N' utilisez pas la pochette avant d'être prêt à effectuer le test.
Lavez vos mains et assurez-vous qu'elles sont propres et sèches avant de commencer le test.
Un éclairage adéquat est nécessaire pour lire le résultat de test.

CONTENU DU KIT

Il existe 4 kits de test, 1 test/kit, 20 tests/kit et 100 tests/kit.
Les composants du kit sont indiqués ci-dessous :

Composants / N° de catalogue		W006P0058	W006P0059	W006P0060	W006P0079
Pochette pour cassette de test	Cassette d'essai (pièces)	1	1x20	1x100	1x20
	Dessiccant (pièces)	1	1x20	1x100	1x20
Accessoires	Compte-gouttes (pièces)	1	1x20	1x100	1x20
	Solution tampon (flacon)	1	1x20	1x100	1x20
	Mode d'emploi (pièces)	1	1x20	1x100	1x20
	Lancette à usage unique (pièces)	1	1x20	1x100	1x20
	Tampon alcoolisé (pièces)	1	1x20	1x100	1x20
	Coton-tige (pièces)	1	1x20	1x100	1x20
	Sac poubelle (pièces)	1	/	/	1x20
	Pansement (pièces)	/	/	/	1x20

Une bandelette de test comprend : conjugué d'or (antigène recombinant de fusion gp41/gp36 du VIH-colloïde d'or et anticorps polyclonal IgG de lapin-colloïde d'or), ligne de test (antigène recombinant gp41 du VIH et antigène recombinant gp36 du VIH) et ligne de contrôle (anticorps polyclonal de chèvre anti-IgG de lapin).

STOCKAGE ET STABILITÉ

1. Le kit de test peut être conservé entre 2 et 30 ° C jusqu'à la date de péremption indiquée sur le kit.
2. Utilisez la cassette de test dans l'heure qui suit l'ouverture de la pochette.
3. Conservez à l'abri de la lumière du soleil, de l'humidité et de la chaleur.
4. Utiliser le kit à 10-30°C.

LIMITES DE LA PROCÉDURE

1. Le test est conçu pour analyser le sang total humain prélevé au doigt.
2. Le test est limité à la détection qualitative des anticorps du VIH-1 et du VIH-2.
3. La procédure de test et l'interprétation des résultats doivent être suivies de près lors du test. Pour une performance optimale du test, un prélèvement correct de l'échantillon est essentiel. Le non-respect de la procédure pourrait entraîner des résultats de test inexacts.
4. Des résultats faussement négatifs peuvent se produire dans les conditions suivantes :
   - Patients exposés au VIH depuis moins de 3 mois.
   - Patients sous traitement anti-VIH (thérapie antirétrovirale).
   - Si la quantité d'anticorps anti-VIH présents dans l'échantillon est inférieure à la limite de détection du test.
5. Des résultats faussement positifs peuvent se produire dans l'échantillon suivantes :
   - Les patients ont participé à un essai clinique de vaccin contre le VIH.
6. La présence de la ligne de contrôle signifie uniquement qu'une migration du liquide ajouté s'est produite. Elle ne garantit pas que :
   - Le bon échantillon a été utilisé.
   - L'échantillon a été correctement appliqué.
7. Comme 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 prestataire de soins de santé en conjonction avec les observations cliniques et les les résultats des autres tests et évaluations de laboratoire. Les résultats du Wondfo HIV Self-Test ne doivent pas être utilisés comme seule base de diagnostic.

CARACTÉRISTIQUES DES PERFORMANCES

Sensibilité et Spécificité :

Une étude clinique du test Wondfo HIV Self-Test a été réalisée dans cinq centres de dépistage différents. Des professionnels de santé ont analysé 3911 échantillons à l' aide de Wondfo HIV Self-Test. Les analyses en laboratoire ont confirmé que 1172 échantillons étaient positifs au VIH et 2739 étaient négatifs.

- Sensibilité : 100 % (IC 95 % : 99,67 % - 100 %) – l' autotest Wondfo HIV Self-Test a correctement détecté l' ensemble des 1172 échantillons positifs.
- Spécificité : 99,96 % (IC 95 % : 99,79 % - 99,99 %) – l' autotest Wondfo HIV Self-Test a correctement identifié 2738 des 2739 échantillons négatifs.

Étude d' Utilisabilité :

Une étude d' utilisabilité a été menée auprès de 900 participants non formés, dont le statut VIH était inconnu, qui ont utilisé eux-mêmes l' autotest Wondfo HIV Self-Test. Le statut réel des participants a été déterminé par un test de laboratoire de 4e génération (Ag/Ac VIH).

- 42 participants (4,7 %) sur les 900 n' ont pas réussi à obtenir un résultat avec l' autotest, dont 5 étaient positifs selon le test de laboratoire. Pour un autre participant, le statut VIH n' a pas pu être établi avant la fin de l' étude.
- Parmi les 72 participants confirmés positifs par le laboratoire, 69 (95,8 %) ont correctement rapporté un résultat positif à l' autotest.
- Parmi les 785 participants confirmés négatifs par le laboratoire, 782 (99,6 %) ont correctement rapporté un résultat négatif à l' autotest.

RÉFÉRENCES

1. WHO. TGS-5 Designing instruction for use for in vitro diagnostic medical devices, Geneva: World Health Organization ; 2019.
2. Medicines and Healthcare products Regulatory Agency. Guidance for notified bodies on the regulation of IVDs for self-testing. London, U.K.: MHRA, Competent Authority (UK); 2012.
3. WHO. TSS-1 Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or selftesting, Geneva: World Health Organization; 2016.

SYMBOLES

IVD Dispositif médical de diagnostic *in vitro*	Consulter le mode d'emploi	Date de péremption
Contient suffisamment pour < *n* > tests	Date de fabrication	Garder au sec
LOT Code du lot	Limite de température	Tenir à l'écart de la lumière du soleil
Fabricant	Ne pas réutiliser	REF Numéro de catalogue
Attention	Ne pas utiliser si l'emballage est endommagé et consulter le mode d'emploi	

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