

**WHO Prequalification of In Vitro Diagnostics  
PUBLIC REPORT**

**Product: One Step HIV1/2 Whole Blood/Serum/Plasma Test  
WHO reference number: PQDx 0357-004-00**

**One Step HIV1/2 Whole Blood/Serum/Plasma Test** with product codes **W006-C4P2, W006-P0045, W006-P0046, W006-P0047, W006-P0048, W006-C4P2-F, W006-P0049, W006-P0050, W006-P0051 and W006-P0052**, 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 29 November 2018.

**Summary of WHO prequalification assessment for  
One Step HIV1/2 Whole Blood/Serum/Plasma Test**

	Date	Outcome
<b>Prequalification listing</b>	29 November 2018	listed
<b>Dossier assessment</b>	26 April 2018	MR
<b>Site inspection(s) of the quality management system</b>	13 February 2024	MR
<b>Product performance evaluation</b>	First quarter of 2018	MR

MR: Meets Requirements

**Report amendments and/or product changes**

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

Version	Summary of amendments	Date of report amendment
2.0	Addition of new product codes to One Step HIV1/2 Whole Blood/Serum/Plasma Test. Alcohol swab and safety lancet/ lancet will be included in the new product codes. Added product codes were, W006-P0045 (25 Tests/Kit), W006-P0046 (25 Tests/Kit), W006-P0047 (25 Tests/Kit), W006-P0048 (25 Tests/Kit), W006-P0049 (40 Tests/Kit), W006-P0050 (40 Tests/Kit), W006-P0051 (40 Tests/Kit) and W006-P0052 (40 Tests/Kit).	6 July 2020

3.0	Correction of product code from WP006-CP42 to W006-C4P2	26 August 2021
4.0	1. Change the manufacturing address of sterile lancet/safety lancet suppliers; 2. Change the supplier of alcohol swabs. 3. Change of alcohol swab labels – removing CE-marking from the current alcohol swab supplier.	5 November 2025

**Intended use:**

According to the manufacturer's claim, "*Wondfo One Step HIV 1/2 Whole Blood/Serum/Plasma Test is a manual qualitative in vitro diagnostic for the detection of HIV 1/2 antibodies in human venous whole blood, capillary whole blood, serum and plasma specimens. It is intended for professional use in either laboratory or point of care settings. It is intended for aiding the diagnosis of HIV infection in symptomatic, symptomatic populations and persons at risk of HIV infection. It is not intended for testing children below 2 years and it is not intended for blood donor screening*".

**Assay description:**

According to the manufacturer's claim, "*Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test is a rapid immunochromatographic direct binding test for the visual detection of HIV antibodies in venous whole blood, fingerstick whole blood, serum or plasma samples in the diagnosis of HIV infection. Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test adopts double antigen sandwich method. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the antigen-dye conjugate, and flows across the HIV antigen pre-coated membrane. When the HIV antibody levels are at or above the detection limit of the test, HIV antibodies in the specimen bind to the antigen-dye conjugate and are captured by antigen immobilized in the test region (T) of the device. This produces a colored test band and indicates a positive result. If no HIV antibodies are present or below the detection limit of the assay, no colored band will be visible in the test region (T) of the device. This indicates a negative result. To serve as a procedure control, a colored line will appear at the control region (C), if the test has been performed properly.*"

**Test kit contents**

Components Catalog No.	Pouch (pcs)	Buffer (bottle)	Instruction (pcs)	Alcohol swab (pcs)	Sterile lancet (pcs)	Safety lancet (pcs)		
						18G	21G	23G
W006-C4P2(25 Tests/Kit)	25	1	1	-	-	-	-	-
W006-P0045 (25 Tests/Kit)	25	1	1	25	25	-	-	-
W006-P0046 (25 Tests/Kit)	25	1	1	25	-	25	-	-
W006-P0047 (25 Tests/Kit)	25	1	1	25	-	-	25	-
W006-P0048 (25 Tests/Kit)	25	1	1	25	-	-	-	25
W006-C4P2-F(40 Tests/Kit)	40	2	1	-	-	-	-	-
W006-P0049 (40 Tests/Kit)	40	2	1	40	40	-	-	-
W006-P0050 (40 Tests/Kit)	40	2	1	40	-	40	-	-
W006-P0051 (40 Tests/Kit)	40	2	1	40	-	-	40	-
W006-P0052 (40 Tests/Kit)	40	2	1	40	-	-	-	40

**Items required but not provided**

- Specimen collection containers
- Centrifuge (for serum/plasma specimen only)
- Capillary tube (for fingerstick whole blood only)
- Timer
- Protective gloves
- Specimen and test waste container

**Storage**

The test kit and sample diluent must be stored at 2 -30 °C.

**Shelf-life upon manufacture**

24 months (test kit and buffer).

**Warnings/limitations**

Refer to the current version of the manufacturer's instructions for use.

### Prioritization for prequalification

Based on the established eligibility criteria, One Step HIV1/2 Whole Blood/Serum/Plasma Test was given priority for WHO prequalification assessment.

### Dossier assessment

Guangzhou Wondfo Biotech Co., Ltd submitted a product dossier for One Step HIV1/2 Whole Blood/Serum/Plasma Test as per the *“Instructions for compilation of a product dossier”* (PQDx\_018 v1). 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 26 April 2018.

Based on the product dossier screening and assessment findings, the product dossier for One Step HIV1/2 Whole Blood/Serum/Plasma Test meets WHO prequalification requirements.

### 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 One Step HIV1/2 Whole Blood/Serum/Plasma Test meets WHO prequalification requirements.

### Product performance evaluation

One Step HIV 1/2 Whole Blood/Serum/Plasma Test (Guangzhou Wondfo Biotech Co., Ltd) was evaluated by WHO in the first quarter of 2018 using serum/plasma specimens. From this evaluation, we drew the following conclusions:

One Step HIV 1/2 Whole Blood/Serum/Plasma Test (Guangzhou Wondfo Biotech Co., Ltd) is a qualitative rapid immunochromatographic assay for the detection of HIV-1/2 antibodies in human serum/plasma and venous/capillary whole blood specimens.

A volume of 10 µL of serum/plasma/whole blood is needed to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually i.e. subjectively read.

In this limited evaluation on a panel of 1199 clinically-derived specimens, we found:

Performance characteristics in comparison with an agreed reference standard		
	Initial (95% CI)	Final (95% CI)
Sensitivity %	100.0% (99.2% - 100.0%)	100.0% (99.2% - 100.0%)
Specificity %	100.0% (99.5% - 100.0%)	100.0% (99.5% - 100%)
Invalid rate %	0%	
Inter-reader variability %	0%	

Lot to lot variation was acceptable for all specimens

Additional performance characteristics	
Sensitivity during seroconversion on eight seroconversion panels in comparison with a benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics)	Seroconversion sensitivity index of -0.125, therefore detection is 0.125 specimens earlier than the benchmark assay.
Analytical sensitivity on a mixed titer panel in comparison with an agreed reference standard	5 of 6 specimens were correctly classified.
Lot to lot variation on a dilution panel in comparison with an agreed reference standard	Acceptable

Key operational characteristics	
Validated specimen types	Serum, plasma (EDTA, heparin or sodium citrate), venous whole blood and capillary whole blood.
Number of steps	2 with precision required
Time to result	15 minutes

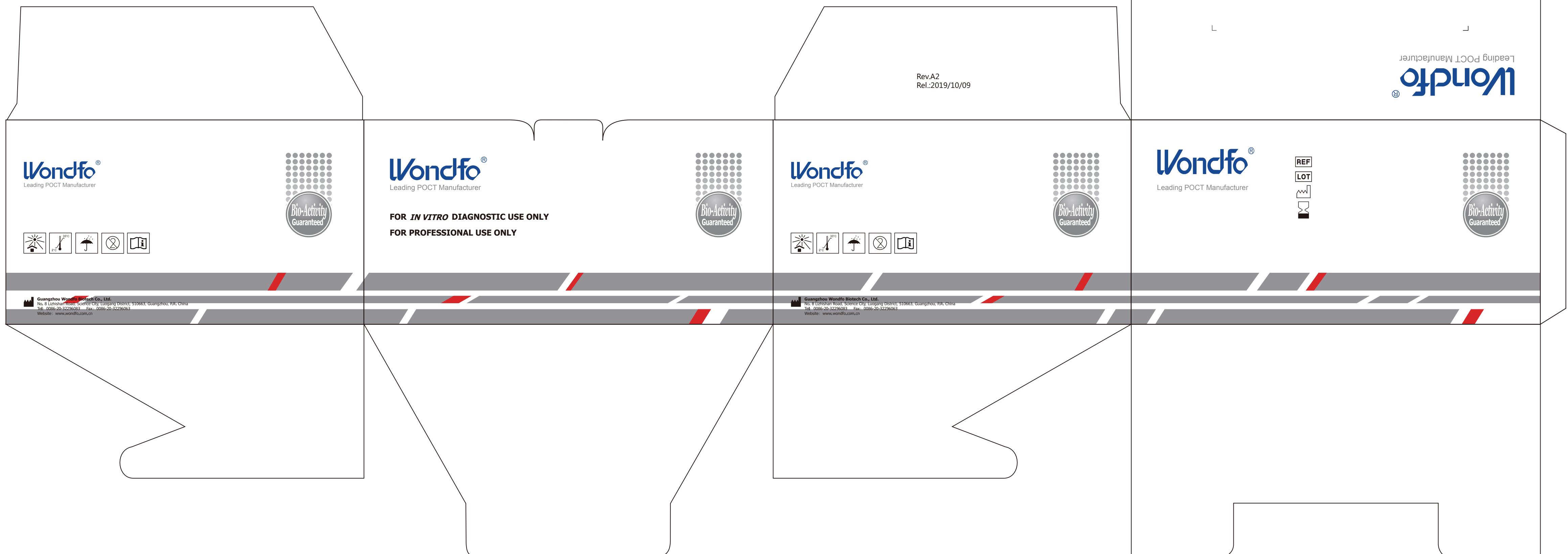
## **Labelling**

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

## **1. Labels**

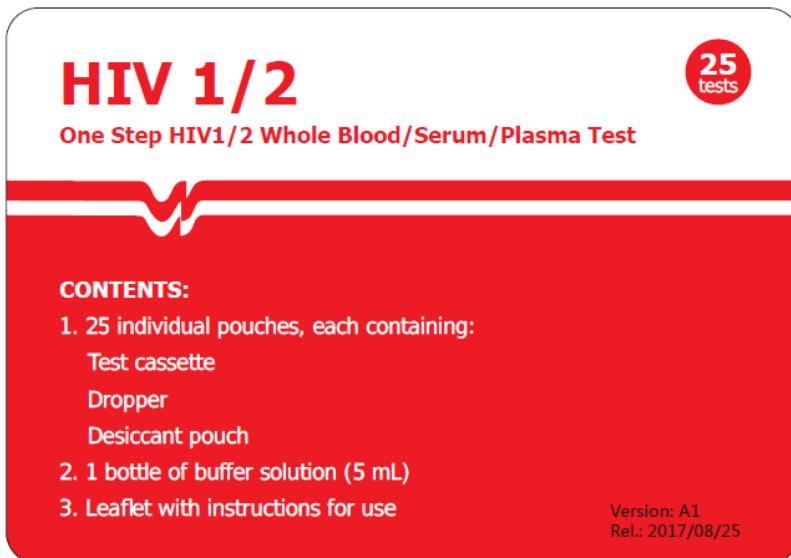
### **1.1 Outside packaging box**

Size: 160\*140\*80mm

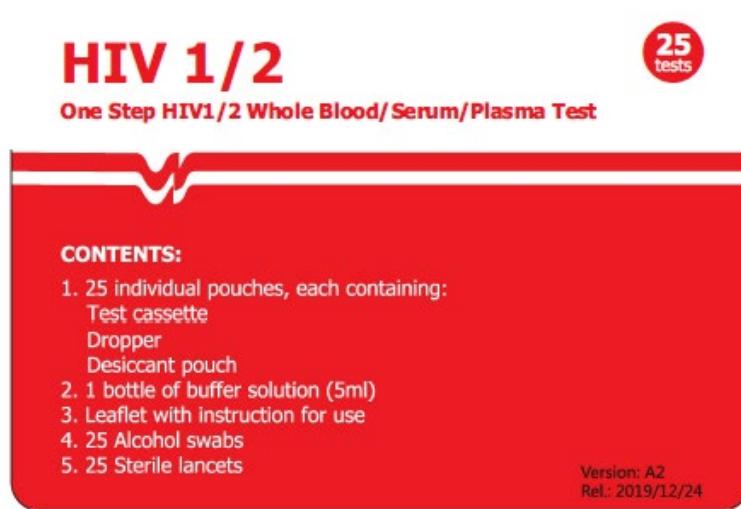


## 1.2 Contents label on outside packaging box

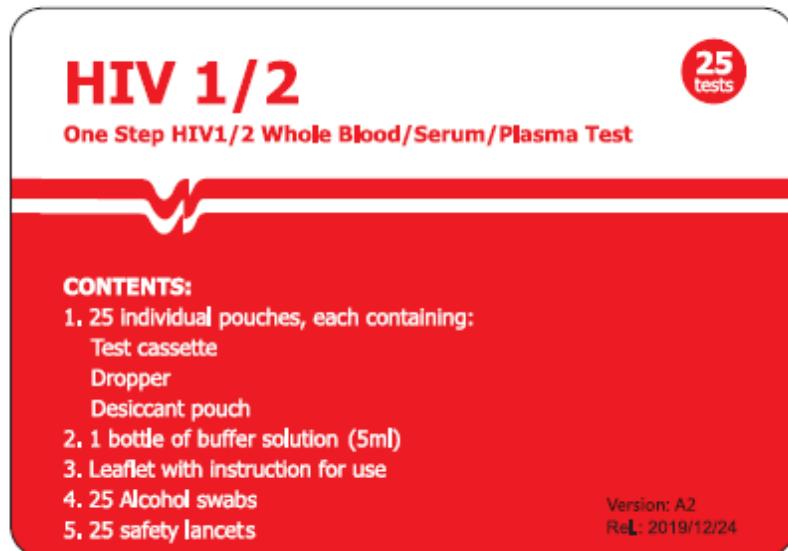
Product code W006-C4P2



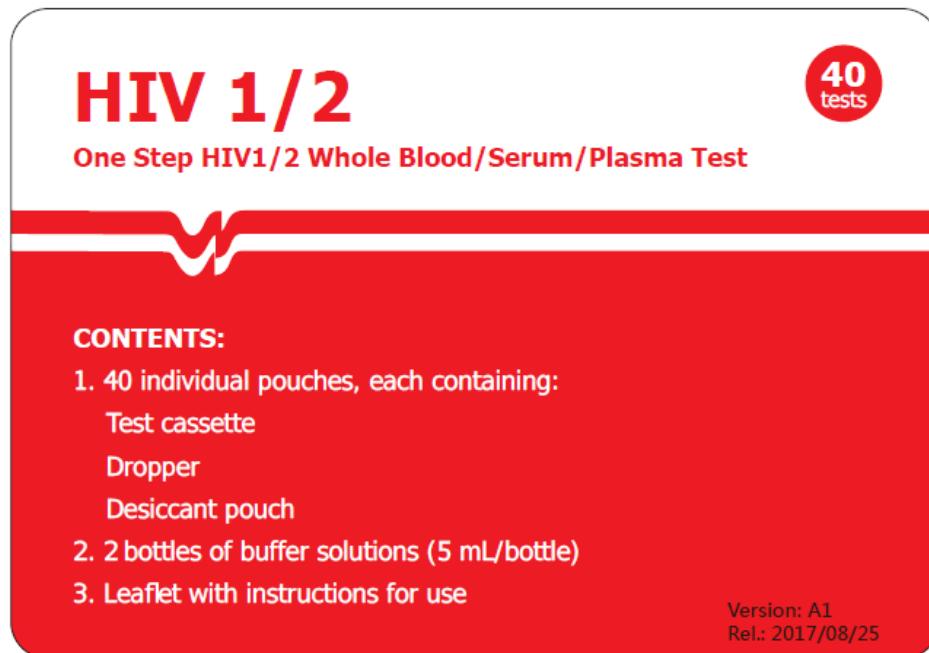
Product code W005-P0045



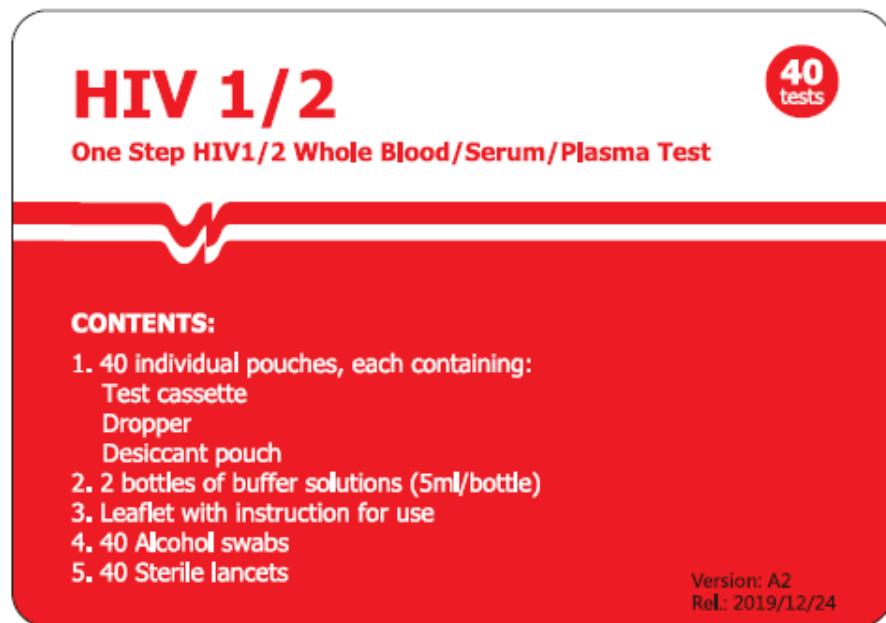
Product codes W006-P0046, W006-P0047 and W006-P0048



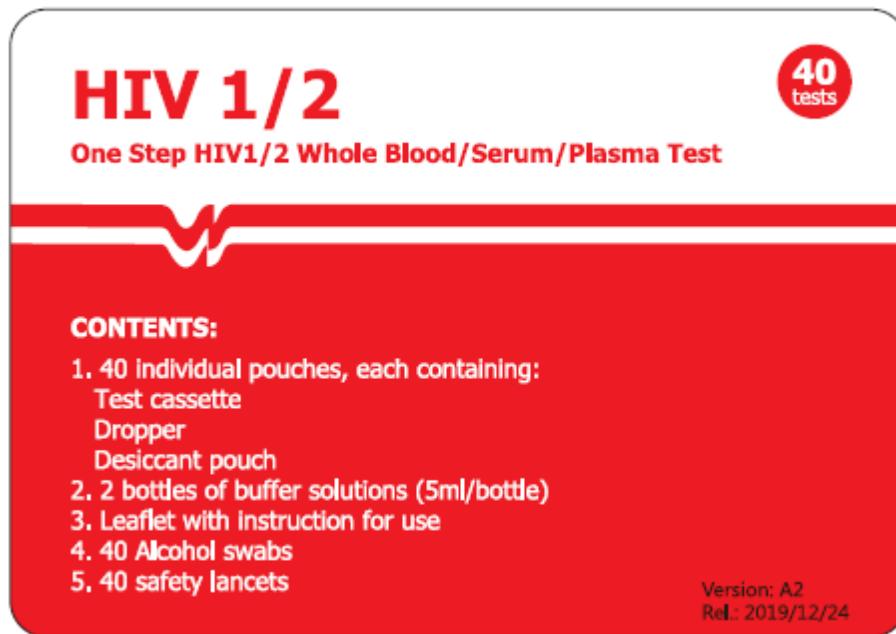
Product code W006-C4P2-F



Product W006-P0049



Product codes W006-P0050, W006-P0051 and W006-P0052



**1.2 Buffer label**

**Buffer for One Step HIV 1/2 Whole  
Blood/Serum/Plasma Test**

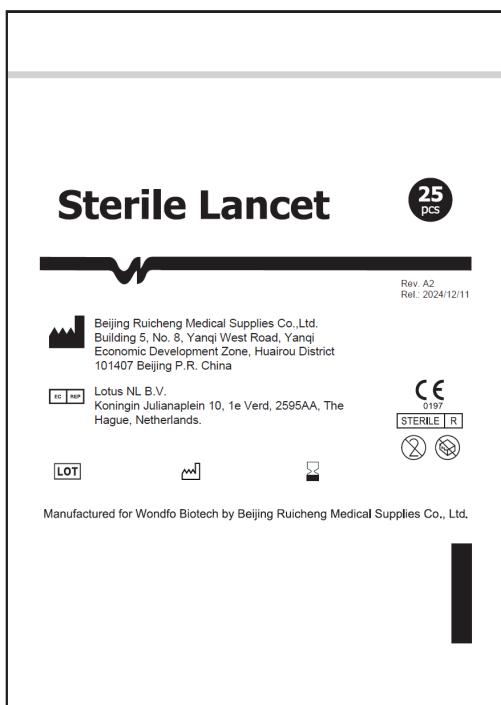
**Lot: XXXXXXXXXX Exp: XXXX/XX/XX  
Vol: 5ml Store at: 2–30°C**

Version: A1 Rel.: 2017/08/25

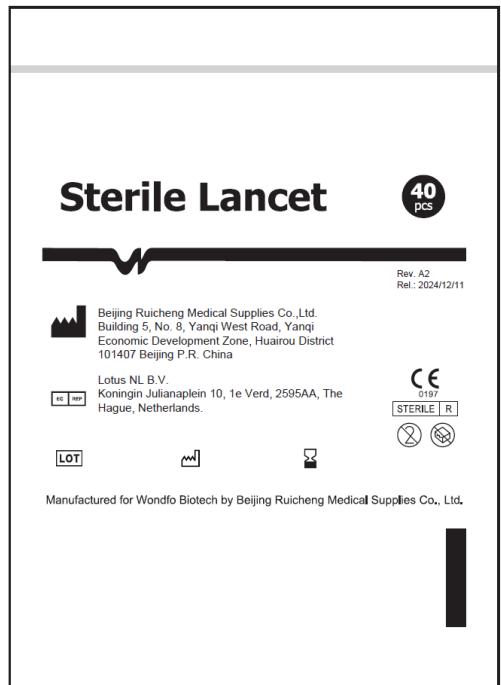
**1.3 Test device package**

**1.4 Sterile lancet label**

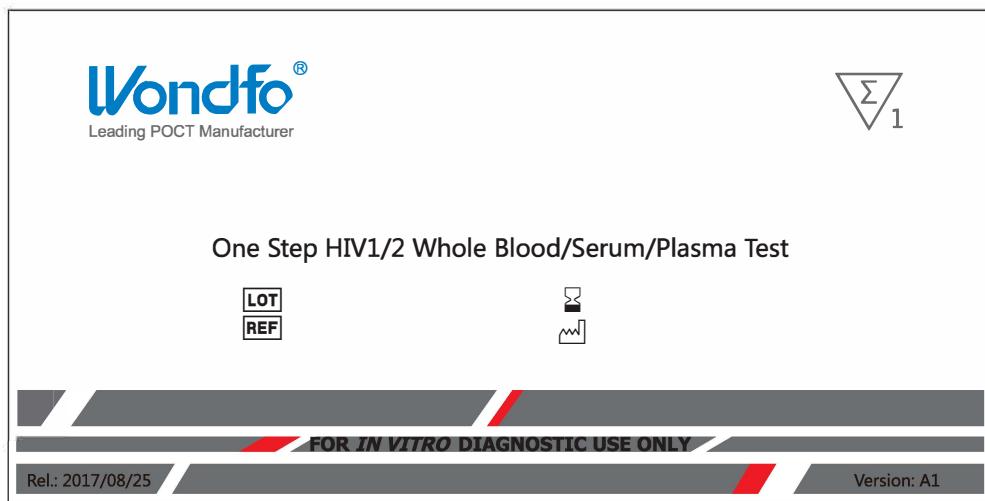
For product code W006-P0045



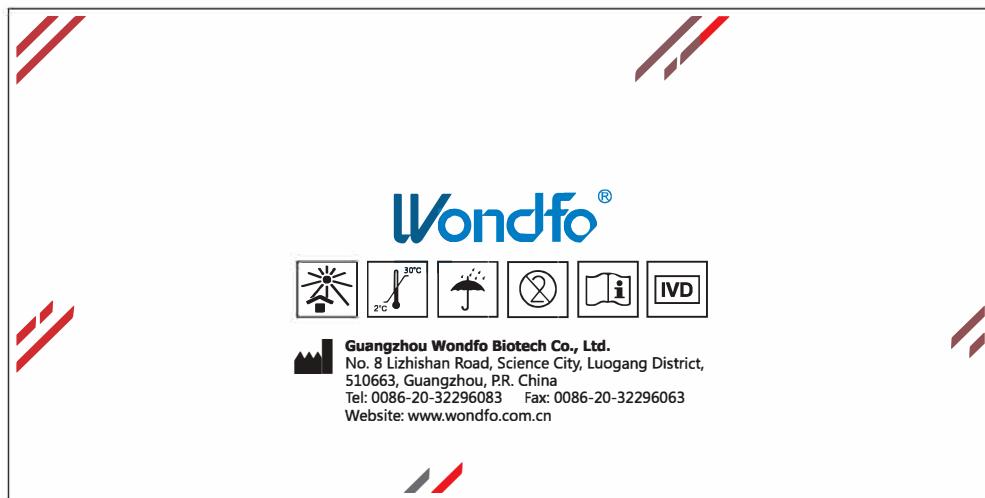
For product code W006-P0049



Front

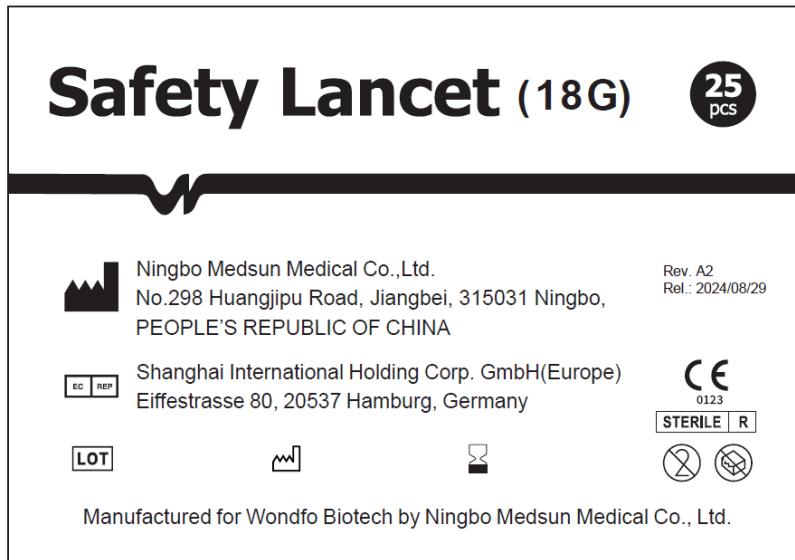


Back

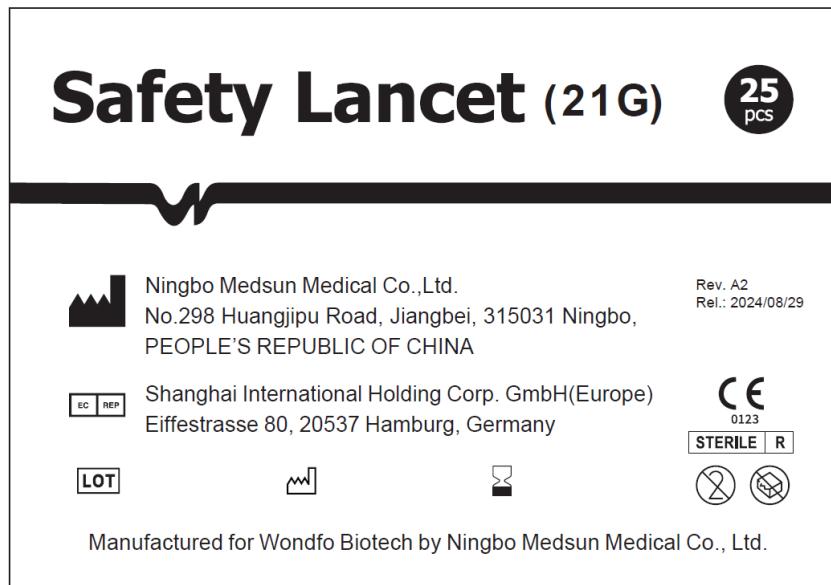


## 1.5 Sterile safety lancet labels

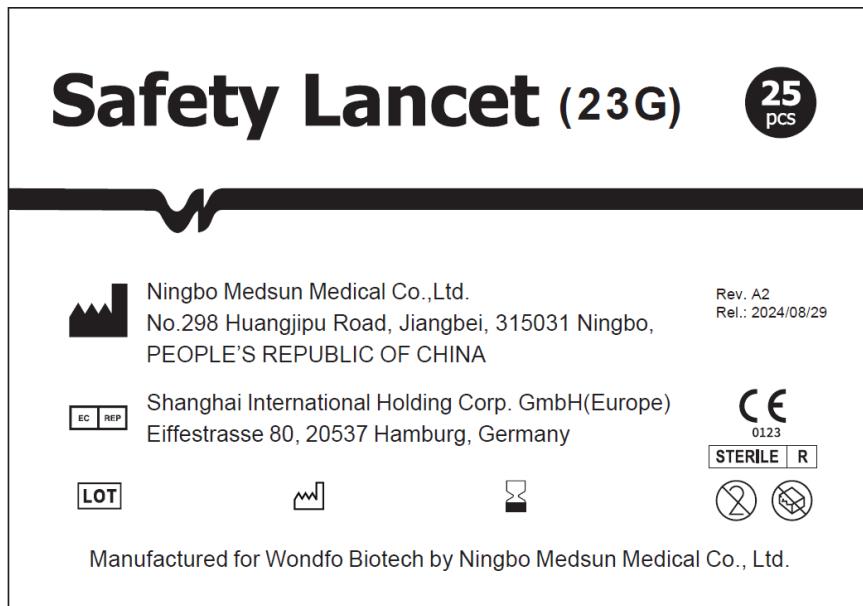
For product code W006-P0046



For product code W006-P0047

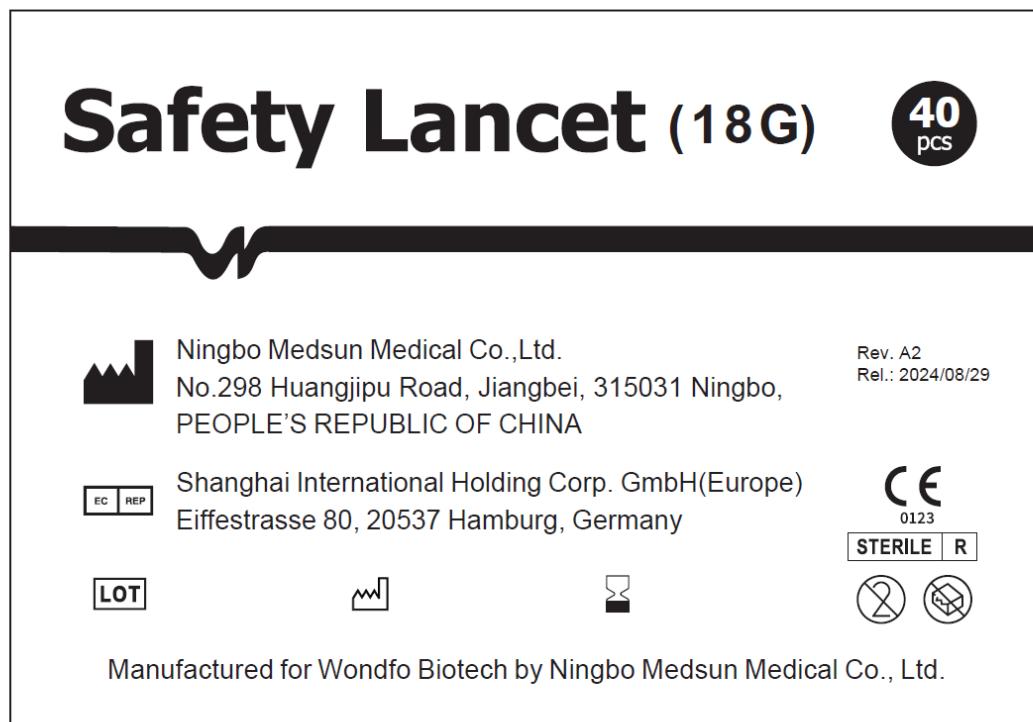


For product code W006-P0048

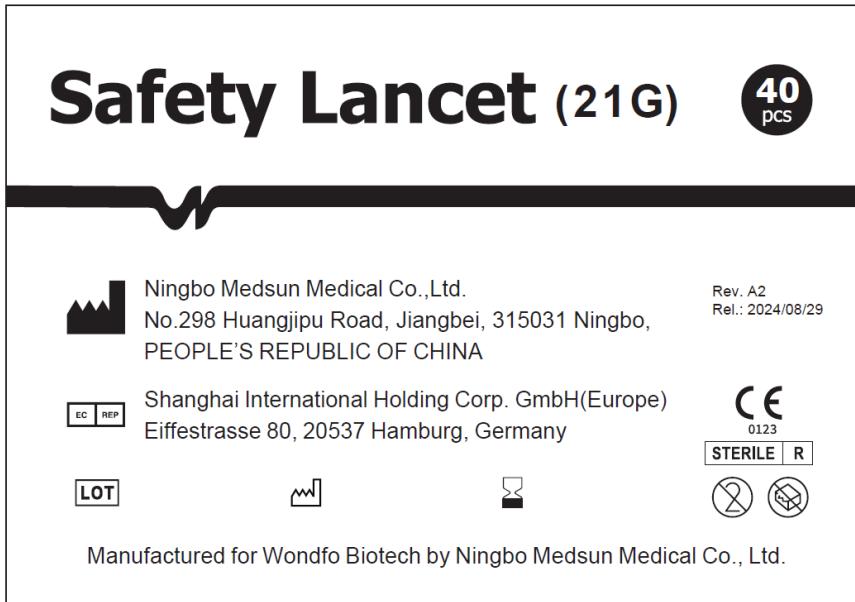


### 1.6 Sterile safety lancets labels

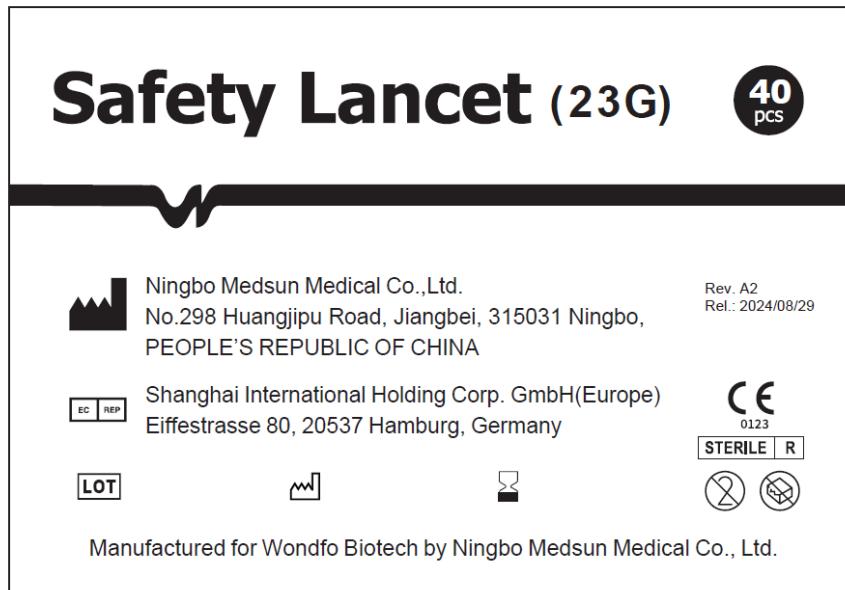
For product codes W006-P0050

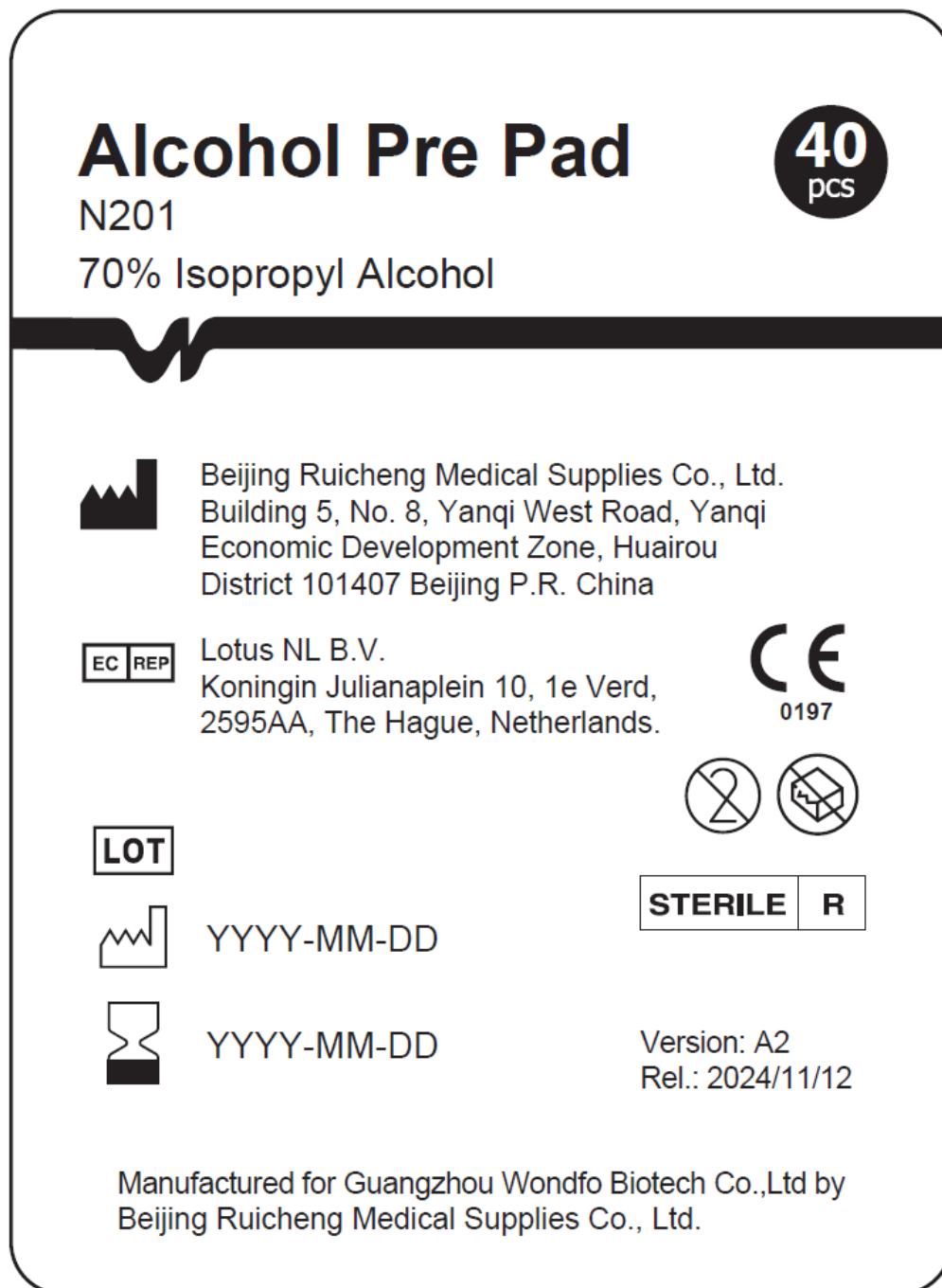


For product code W006-P0051



For Product code W006-P0052



**1.7 Alcohol swab label**

## **2.0 Instructions for use<sup>1</sup>**

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<sup>1</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.

 <b>One Step HIV1/2 Whole Blood/Serum/Plasma Test</b>		<b>Catalog No.</b> W006-C4P2 (25Tests) W006-C4P2-F(40tests) W006-P0045 (25Tests) W006-P0049 (40Tests) W006-P0046 (25Tests) W006-P0050 (40Tests) W006-P0047 (25Tests) W006-P0051 (40Tests) W006-P0048 (25Tests) W006-P0052 (40Tests)	<b>PRINCIPLE OF THE PROCEDURE</b> <p>Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test is a rapid immunochromatographic direct binding test for the visual detection of HIV antibodies in venous whole blood, fingerstick whole blood, serum or plasma samples in the diagnosis of HIV infection. Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test adopts double antigen sandwich method. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the antigen-dye conjugate, and flows across the HIV antigen pre-coated membrane.</p> <p>When the HIV antibody levels are at or above the detection limit of the test, HIV antibodies in the specimen bind to the antigen-dye conjugate and are captured by antigen immobilized in the test region (T) of the device. This produces a colored test band and indicates a positive result.</p> <p>If no HIV antibodies are present or below the detection limit of the assay, no colored band will be visible in the test region (T) of the device. This indicates a negative result.</p> <b>CONTENT OF THE KIT</b> <p><b>A. Kit components</b>          Each individual sealed pouch contains one test cassette, one dropper and one desiccant pouch (for storage purposes only). Each test cassette contains one plastic cassette and one test strip.</p> <p>The different article Number are as follows:</p> <p><b>WARNINGS AND PRECAUTIONS</b></p> <ol style="list-style-type: none"> <li>This assay has been evaluated on EDTA, heparin, and sodium citrate. Other anticoagulants are excluded.</li> <li>Read the Instructions for Use before using this product. The instructions must be followed carefully as not doing so may result in inaccurate results.</li> <li>Wear protective clothing such as laboratory coat, safety glasses and disposable gloves when handling specimens.</li> <li>Wash hands thoroughly after use. Not intended for use in screening blood and tissue donors. This assay has not been evaluated for neonate or cord blood specimens.</li> <li>This kit is for <i>in vitro</i> diagnosis of the infection of HIV only, this assay will not provide a diagnosis for any other disease.</li> <li>Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.</li> <li>All specimens should be treated as potentially infectious.</li> <li>EBV IgM positive specimens may cause erroneous results.</li> <li>Discard test cassette, dropper, desiccant pouch after first use. The test can not be used more than once.</li> <li>Cap and tightly the opened buffer after using.</li> <li>Do not use the kit beyond the expiration date.</li> <li>Do not use the kit if the pouch is punctured or not well sealed. Do not mix buffer /test devices from different kit lots.</li> <li>Keep out of the reach of children.</li> <li>All specimens and used-devices have infectious risks. The disposal process must follow the local infectious disposal law or laboratory rules.</li> </ol>																																																																																																				
<b>INTENDED USE</b> <p>Wondfo® One Step HIV 1/2 Whole Blood/Serum/Plasma Test is intended for use by trained users (in either laboratory or point-of-care settings), and is a qualitative, screening, <i>in vitro</i> diagnostic test for detection of HIV 1/2 antibodies in human venous whole blood, fingerstick whole blood, serum or plasma, aid to diagnosis of HIV infection.</p>	<b>SUMMARY AND EXPLANATION OF THE TEST</b> <p>HIV (human immunodeficiency virus) is the pathogen of AIDS (acquired immunodeficiency syndrome). HIV belongs to Retroviridae genus Lentivirus family, and there are two groups of HIV, HIV-1 and HIV-2. HIV-1 is highly mutagenic and can be divided into 9 subtypes by the mutations in its membrane protein, which are A, B, C, D, E, F, G, H and O. HIV-2 has 60% nucleotide acid homology with HIV-1, but they are different in their ability of infection, HIV-1 is the most prevailing virus strain. Once infected, it mutates quickly and has bad prognosis. HIV-2 has a longer latent period, and relative weaker in its pathogenesis.</p>	<b>Rev. A7</b>																																																																																																					
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<b>CONTENTS OF THE KIT</b> <p><b>For W006-P0046, W006-P0047, W006-P0048, W006-P0050, W006-P0051 and W006-P0052:</b></p> <ol style="list-style-type: none"> <li>Specimen collection containers</li> <li>Centrifuge (for serum/plasma specimen only)</li> <li>Timer</li> <li>Protective gloves</li> <li>Specimen and test waste container</li> </ol> <p><b>For W006-C4P2(25 Tests/Kit) and W006-C4P2-F(40 Tests/Kit):</b></p> <ol style="list-style-type: none"> <li>Specimen collection containers</li> <li>Sterile lancets</li> <li>Alcohol Swabs</li> <li>Centrifuge (for serum/plasma specimen only)</li> </ol>	<b>Components</b> <table border="1"> <thead> <tr> <th rowspan="2">Catalog No.</th> <th rowspan="2">Pouch (pcs)</th> <th rowspan="2">Buffer (bottle)</th> <th rowspan="2">Instruction (pcs)</th> <th rowspan="2">Alcohol swab (pcs)</th> <th rowspan="2">Sterile lancet (pcs)</th> <th colspan="3">Safety lancet (pcs)</th> </tr> <tr> <th>18G</th> <th>21G</th> <th>23G</th> </tr> </thead> <tbody> <tr> <td>W006-C4P2(25 Tests/Kit)</td> <td>25</td> <td>1</td> <td>1</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>W006-P0045 (25 Tests/Kit)</td> <td>25</td> <td>1</td> <td>1</td> <td>25</td> <td>25</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>W006-P0046 (25 Tests/Kit)</td> <td>25</td> <td>1</td> <td>1</td> <td>25</td> <td>-</td> <td>25</td> <td>-</td> <td>-</td> </tr> <tr> <td>W006-P0047 (25 Tests/Kit)</td> <td>25</td> <td>1</td> <td>1</td> <td>25</td> <td>-</td> <td>-</td> <td>25</td> <td>-</td> </tr> <tr> <td>W006-P0048 (25 Tests/Kit)</td> <td>25</td> <td>1</td> <td>1</td> <td>25</td> <td>-</td> <td>-</td> <td>-</td> <td>25</td> </tr> <tr> <td>W006-C4P2-F(40 Tests/Kit)</td> <td>40</td> <td>2</td> <td>1</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>W006-P0049 (40 Tests/Kit)</td> <td>40</td> <td>2</td> <td>1</td> <td>40</td> <td>40</td> <td>-</td> <td>-</td> <td>-</td> </tr> <tr> <td>W006-P0050 (40 Tests/Kit)</td> <td>40</td> <td>2</td> <td>1</td> <td>40</td> <td>-</td> <td>40</td> <td>-</td> <td>-</td> </tr> <tr> <td>W006-P0051 (40 Tests/Kit)</td> <td>40</td> <td>2</td> <td>1</td> <td>40</td> <td>-</td> <td>-</td> <td>40</td> <td>-</td> </tr> <tr> <td>W006-P0052 (40 Tests/Kit)</td> <td>40</td> <td>2</td> <td>1</td> <td>40</td> <td>-</td> <td>-</td> <td>-</td> <td>40</td> </tr> </tbody> </table>	Catalog No.	Pouch (pcs)	Buffer (bottle)	Instruction (pcs)	Alcohol swab (pcs)	Sterile lancet (pcs)	Safety lancet (pcs)			18G	21G	23G	W006-C4P2(25 Tests/Kit)	25	1	1	-	-	-	-	-	W006-P0045 (25 Tests/Kit)	25	1	1	25	25	-	-	-	W006-P0046 (25 Tests/Kit)	25	1	1	25	-	25	-	-	W006-P0047 (25 Tests/Kit)	25	1	1	25	-	-	25	-	W006-P0048 (25 Tests/Kit)	25	1	1	25	-	-	-	25	W006-C4P2-F(40 Tests/Kit)	40	2	1	-	-	-	-	-	W006-P0049 (40 Tests/Kit)	40	2	1	40	40	-	-	-	W006-P0050 (40 Tests/Kit)	40	2	1	40	-	40	-	-	W006-P0051 (40 Tests/Kit)	40	2	1	40	-	-	40	-	W006-P0052 (40 Tests/Kit)	40	2	1	40	-	-	-	40
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<b>PRINCIPLE OF THE PROCEDURE</b>	<b>Rev. A7</b>	<b>SERUM and Plasma</b> <ol style="list-style-type: none"> <li>The kit and the unused buffer must be stored at 2°C-30°C before expiration date; the opened buffer should store at 2°C-30°C, no more than 8 weeks.</li> <li>Use the kit within 1 hour once the pouch is opened.</li> <li>Use the kit under the condition of the humidity from 20% to 90% and the temperature from 10°C to 30°C.</li> <li>Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature within 4 hours. Specimens should be stored at 2°C-8°C if the test is to be run within 7 days of collection. If testing is delayed more than 7 days, the specimen should be frozen (-20°C or colder).</li> <li>Keep away from sunlight, moisture, and heat.</li> <li>Do not freeze.</li> </ol>																																																																																																					
<b>INTENDED USE</b>	<b>Rev. A7</b>	<b>INTERPRETATION OF TEST RESULTS</b>																																																																																																					
<b>CONTENTS OF THE KIT</b>	<b>Rev. A7</b>	<b>COLLECTING AND PREPARING SPECIMENS</b>																																																																																																					
<b>WARNINGS AND PRECAUTIONS</b>	<b>Rev. A7</b>	<b>Whole blood – Collected by venipuncture</b> <ol style="list-style-type: none"> <li>Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (containing EDTA, citrate, or heparin).</li> <li>It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature (10°C to 30°C) within 4 hours. If the specimens are not tested immediately, they may be stored at 2°C-8°C for up to 7 days, only. It's not suitable to test the whole blood samples which have been stored at 2°C-8°C for more than 7 days.</li> <li>Equilibrate all specimens and the device to room temperature (10°C ~30°C) before testing.</li> <li>Remove a test cassette from the pouch by tearing the notch and place it on a level surface.</li> <li>Use the specimen of either serum, plasma, or whole blood (collected by venipuncture). Slowly add 10μL (the second mark line of the dropper) of specimen to the sample well A and then add 2 drops of buffer to the buffer well B.</li> <li>Use the specimen of whole blood (collected by fingerstick): collecting the specimen by capillary tube (not provided), slowly add 10μL of specimen to the sample well A and then add 2 drops of buffer to the buffer well B.</li> <li>Incubate the cassette at room temperature (10°C-30°C) and read the result after 15 minutes, but not more than 30 minutes. Reading the test before 15 minutes or after 30 minutes may cause false result.</li> </ol>																																																																																																					
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2. Specimen less than 5 $\mu$ L (the first mark line of the dropper) or more than 15 $\mu$ L (the third mark line of the dropper) may cause incorrect results.

3. The test result will be incorrect when adding the specimen and buffer in wrong position or sequence.

## PERFORMANCE CHARACTERISTICS

### 1. Analytical performance study - Interfering substances

Summary of test results for determination of analytical specificity: potentially interfering substances.

#### A. Specimens of HIV-1 positive

Potentially interfering substance	Number	Number of erroneous result	
		Not spiked with anti-HIV <sup>1</sup> positive specimen	Spiked with anti-HIV positive specimen
Alcohol	6	0	0
Haemoglobin	4	0	0
Direct bilirubin	7	0	0
Total bilirubin	17	0	0
Triglyceride	17	0	0
High-cholesterol	9	0	0
Low density lipoprotein	15	0	0
Rheumatic factor	25	0	0
IgM gammopathies	10	0	0
IgG gammopathies	2	0	0
Pregnant women	31	0	0
Systemic lupus erythematosus (SLE)	8	0	0
Anti-nuclear antibodies (ANA)	8	0	0
Anti-escherichia coli	2	0	0
Total	161	0	0

### 2. Analytical performance study - Cross reactivity

Summary of test results for determination of analytical specificity: potentially cross-reacting unrelated infections and diseases.

Potentially cross-reacting substance	Number	Number of erroneous result
Malaria	27	0
Epstein-Barr virus immunoglobulin(EBV IgM) <sup>1</sup>	5	2
Epstein-Barr virus immunoglobulin(EBV IgM) <sup>2</sup>	60	0
Influenza antibody	13	0
Cytomegalovirus immunoglobulin M(CMV IgM)	5	0
Syphilis	5	0
Herpes simplex virus(HSV)	5	0
Anti-HBc	15	0
Ant-HBs	15	0
Anti-HCV	15	0
Anti-HTLV 1/2	15	0
Anti-HEV	10	0
Total	185	2

#### NOTE:

1. Testing in the third party Institute of Tropical Medicine
2. Testing in Guangzhou Wondfo Biotech Co.,Ltd.

### 3. Analytical performance study - Analytical sensitivity

A total of 45 HIV seroconversion panels were tested, 25 of which were tested by Wondfo and 20 were tested by a third party institution. Among the 25 HIV seroconversion panels tested by Wondfo with a commercially available WHO prequalified HIV ELISA reagent as reference assay, HIV antibody in 6 panels was detected by Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test earlier than that by the ELISA; HIV antibody in 2 panels that detected by Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test were later than that by the ELISA; and HIV antibody in 17 panels were detected by both assays at the same bleeding.

For the 20 HIV seroconversion panels tested by the third party institution, 4 CE marked HIV ELISA reagents were set as reference assay. From the 111 seroconversion panel members, the One Step HIV 1/2 Whole Blood/Serum/Plasma Test detected 18 samples more than the least sensitive CE marked antibody test and 4 samples less than the most sensitive CE marked antibody test.

### 4. Analytical performance study - HIV-1 subtypes positive specimens

The HIV-1 Worldwide Performance Panel, the WHO International Standard HIV (antibody), 1st International Panel (NIBSC code: 02/210) and 50 specimens with various subtypes (10 specimens for each of subtypes A1, B, C, CRF02\_AG and G) were tested by Wondfo. And 40 specimens with various subtypes were tested by a third party institution, including 3 specimens for each of following subtypes: C, CRF01\_AE, CRF02\_AG, CRF06\_cpx, CRF36\_cpx, D, G, group O, H, J, and K, 2 specimens for subtypes A, F1 and F2, and 1 specimen for subtype A1.

Wondfo One Step HIV1/2 Whole Blood/Serum/Plasma Test can detect HIV-2 antibodies and the following subtypes of HIV-1 antibodies: Group O, subtype A, subtype A1, subtype B, subtype C, subtype D, subtype F1, subtype F2, subtype H, subtype J, subtype K, subtype G, CRF01-AE, CRF02\_AG, CRF06\_cpx, CRF36\_cpx and CRF02-AG.

### 5. Clinical performance study - Diagnostic sensitivity

Summary of results of a clinical study to determine diagnostic sensitivity.

Specimens type	No. of specimens	False negative	Sensitivity	95% Confidence Interval
Serum	456	0	100%	(99.18, 100)
Plasma	620	0	100%	(99.38, 100)
Whole venous blood	100	0	100%	(96.30, 100)
Total	1176	0	100%	(99.67, 100)

### B. Specimens of HIV-2 positive

#### SYMBOLS KEY

Specimens type	No. of specimens	False negative	Sensitivity	95% Confidence Interval
Plasma	100	0	100%	(96.30, 100)

 IVD	In vitro diagnostic medical device
 Consult Instructions for Use	
 Expiry Date	
 $\Sigma$	Content sufficient for < n > tests
 Date of manufacture YYYY-MM-DD	
 Keep dry	
 LOT	Batch code
 $20^{\circ}\text{C}$	Temperature limit
 Keep away from sunlight	
 	Indicates the device manufacturer
 REF	Product code/ Catalogue number
 Caution	

Guangzhou Wondfo Biotech Co., Ltd.  
No.8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R.China  
Tel: +86-20-32296083 400-888-5268(Toll Free)  
Fax: +86-20-32296063  
E-mail: sales@wondfo.com.cn  
Website: www.wondfo.com.cn

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