ENGLISH

Rev. A6 Rel.: 2022/7/11

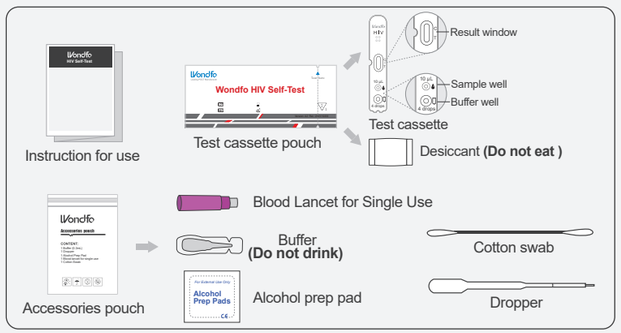
Wondfo HIV Self-Test

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

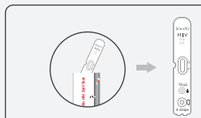
Contents



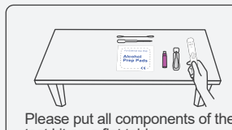
Materials may be required but not provided.

Timer Tissue Bandage

Preparation

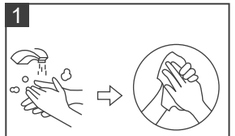


Open test cassette pouch.

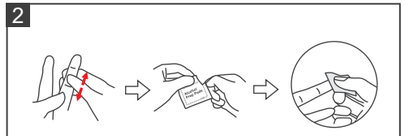


Please put all components of the test kit on a flat table.

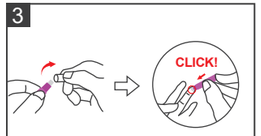
How to use the test kit (for fingerstick whole blood use)



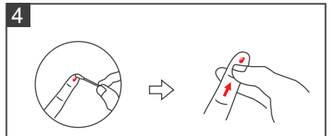
Wash your hands and dry them before testing.



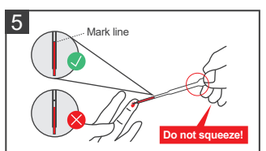
Squeeze finger until warm. Open the alcohol prep pad. Clean the finger with alcohol prep pad.



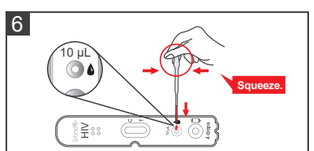
Take off the lancet cap and prick the fingertip by pushing against it.



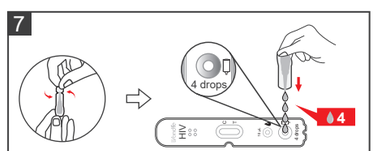
Wipe off the first drop of blood with the cotton swab. Squeeze the finger to create a full drop of blood.



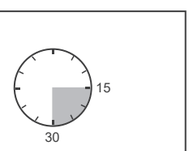
Do not squeeze the dropper, hold the tip to the blood and fill to mark line.



Squeeze the top of the dropper and add all of the blood into the specimen well.



Twist off the buffer tip as the picture shows. Add **4 drops** of buffer into the buffer well.

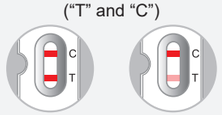


Read the results after **15 minutes** but no more than **30 minutes**.

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 instruments.
- 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

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 3 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
Test cassette pouch	Test cassette (pcs)	1	1x20	1x100
	Desiccant (pcs)	1	1x20	1x100
Accessories	Dropper (pcs)	1	1x20	1x100
	Buffer (vial)	1	1x20	1x100
	IFU (pcs)	1	1x20	1x100
	Blood Lancet for Single Use (pcs)	1	1x20	1x100
	Alcohol prep pad (pcs)	1	1x20	1x100
	Cotton swab (pcs)	1	1x20	1x100
	Disposal bag (pcs)	1	/	/

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 for 24 months.
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 detecting 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

In the clinical study, 900 participants whose HIV status were unknown were given the Wondfo HIV Self-Test to test. The results were compared to the 4th generation laboratory test. The laboratory results shown that a total of 77 participants were HIV positive, 822 participants were HIV negative and 1 undetemined. A total of 43 participants (5 HIV positive, 37 HIV negative and 1 undetermined) were excluded from the performance analysis. The comparison of results was as follows:

- 95.8% of participants (69/72) correctly reported the result as positive. This means that 3 participants infected with HIV reported negative result. This is called a false negative.
- 99.6% of participants (782/785) correctly reported the result as negative. This means that 3 participants not infected with HIV reported positive result. This is called a false positive.
- 4.7% of participants (42/900) failed to obtain a result, 1 participant's HIV infection status was not confirmed during the clinical study so it was excluded from the analysis.

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	Expiry date YYYY-MM-DD
Contains sufficient for < *n* > tests	Date of manufacture YYYY-MM-DD	Keep dry
LOT Batch code	Temperature limit	Keep away from sunlight
Manufacturer	Do not re-use	REF Product code/ Catalogue number
Caution		

Manufacturer information

Guangzhou Wondfo Biotech Co., Ltd.

Add: 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: global@wondfo.com.cn
Website: www.wondfo.com.cn

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