WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

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

Wondfo HIV Self-Test with product codes W006P0058, W006P0059, and W006P0060**,** 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 prequalification assessment for 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
Site inspection(s) of the quality management system	12 October 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 occurred. 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	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

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."*

Assay Description:

According to the claim of assay description from Guangzhou Wondfo Biotech Co., Ltd, "Wondfo HIV Self-Test adopts double antigen sandwich immunochromatography method. Once the specimen and the buffer are added into their respective wells, they migrate along the device by capillary action. When the levels of HIV-1 or HIV-2 antibodies are at or above the target cut-off level, HIV-1 and/or HIV-2 antibodies bind to the colloidal gold-HIV antigen(gp36/41). The complex is captured by HIV recombinant antigen (gp41and gp36) immobilized in the test region (T). This produces a visible colored band in the test region (T) and indicates a positive result. When the levels of HIV 1/2 antibody are zero or below the target cut-off level, there is no visible colored band in the test region (T). This indicates a negative result. To serve as an internal 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.		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	/	/

Materials required but not provided:

- Timer
- Tissue
- Bandage.

Storage

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

Shelf-life upon manufacture

24 months (test kit and buffer).

Warnings/limitations

Refer to manufacturer's instructions for use.

Labelling

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

1. Labels

1.1 Labels for product code W006P0058

Rev. A4 Rel.: 2023/03/31

Wondfo

Leading POCT Manufacturer

Contents:

1 Test cassette
1 Dropper
1 Buffer
1 Alcohol Prep Pad
1 Disposal bag
1 Desiccant pouch
1 Instruction for use (IFU)
1 Cotton swab
1 Blood Lancet for Single Use

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

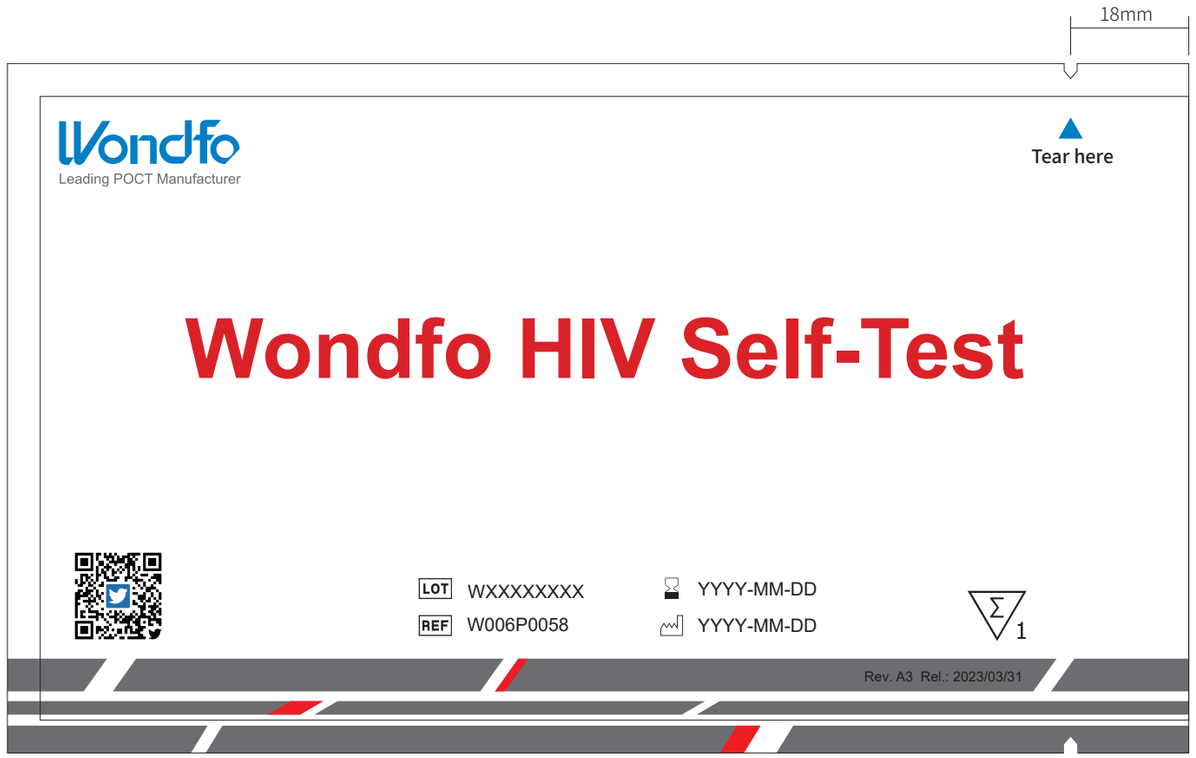
Σ 1 IVD

Wondfo
Leading POCT Manufacturer

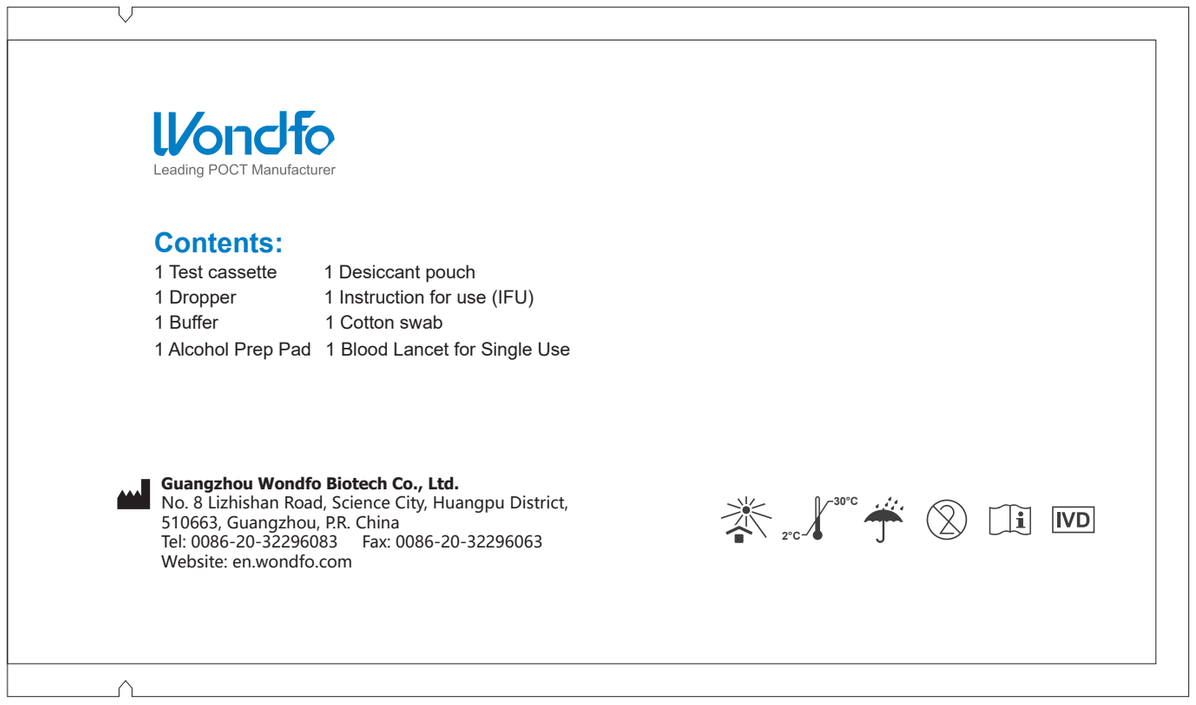
Guangzhou Wondfo Biotech Co., Ltd.
Add:No. 8 Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R. China
Tel:0086-20-32296083 Fax:0086-20-32296063 Website: en.wondfo.com

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



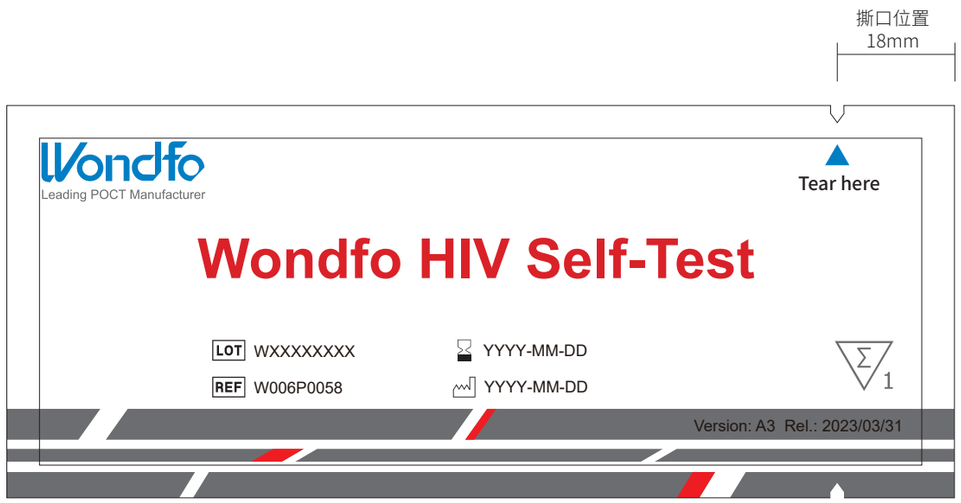
Back



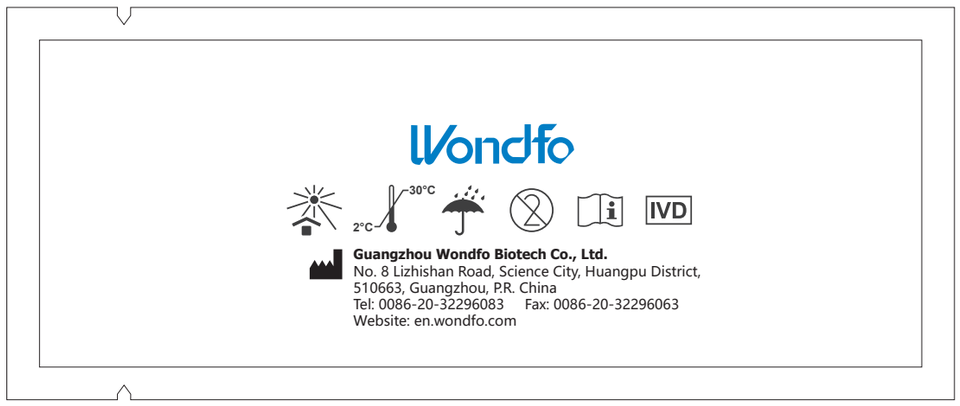
Foil Pouch for W006P0058

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

Front



Back



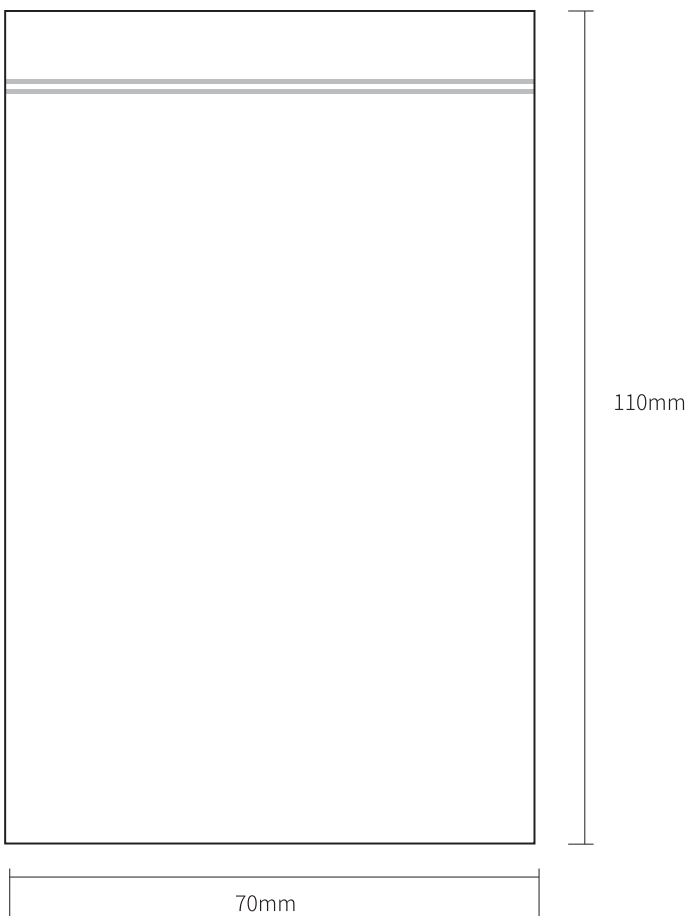
Test Cassette Foil Pouch for W006P0058

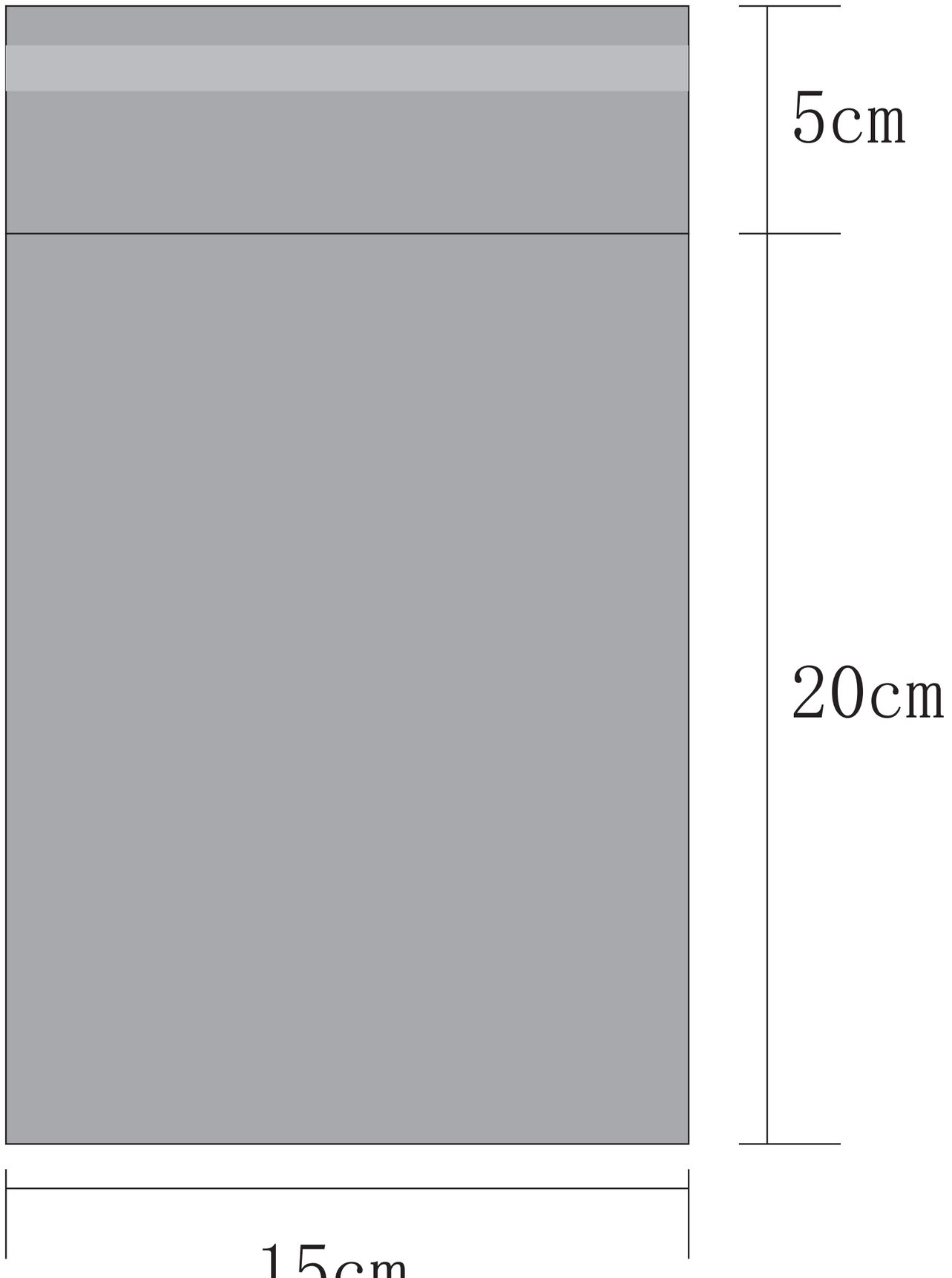
Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.

Front

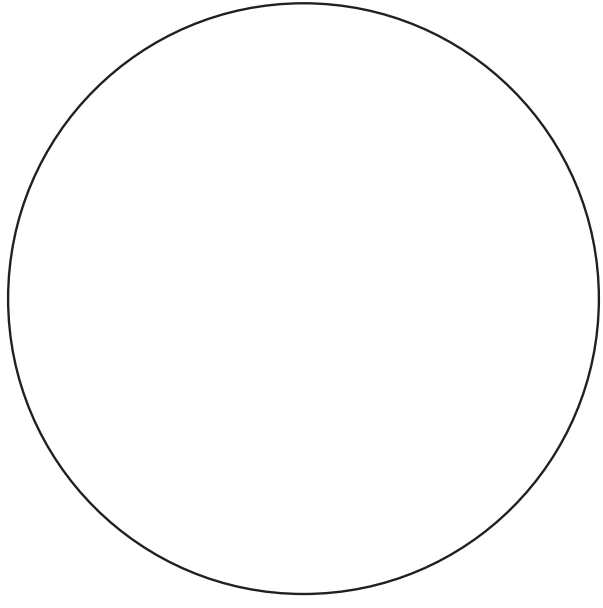

自封口
10mm
Wondfo
Accessories pouch
CONTENT:
1 Buffer (0.3mL)
1 Dropper
1 Alcohol prep pad
1 Blood Lancet for Single Use
1 Cotton swab
Version: A1
Rel.: 2023/03/31

Back


110mm
70mm



Disposal Bag for W006P0058

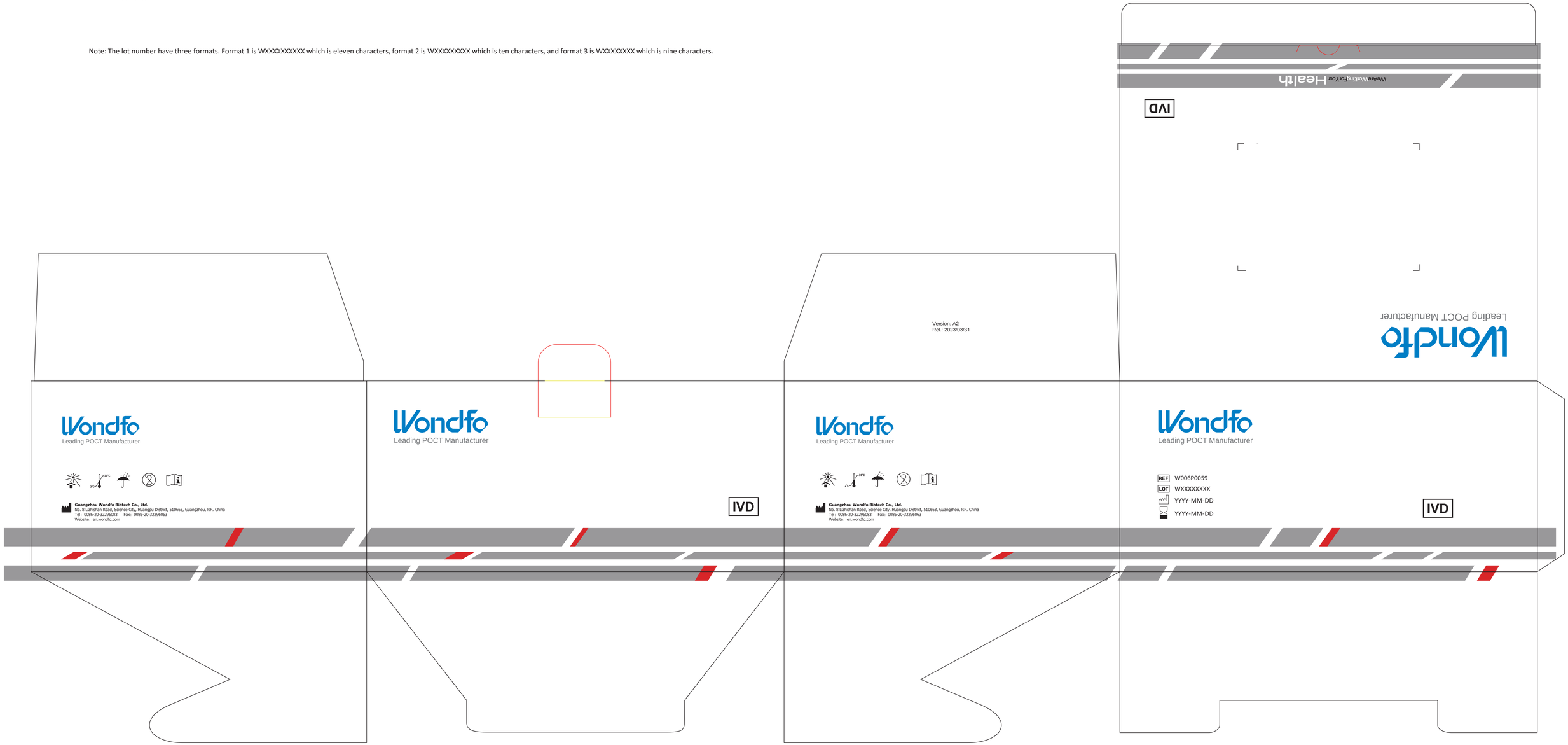


Round Sticker

1.2 Labels for product code W006P0059

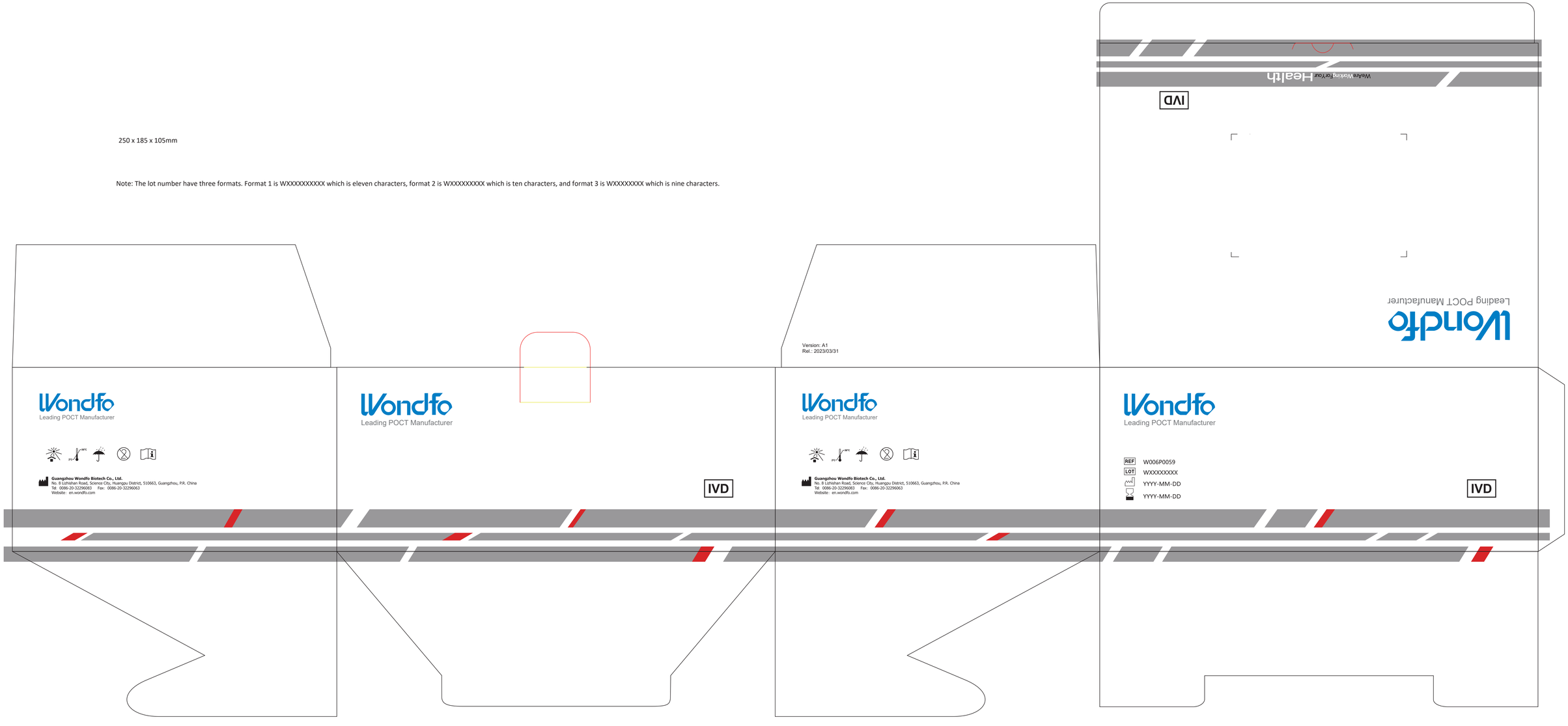
230 x185x 105 mm

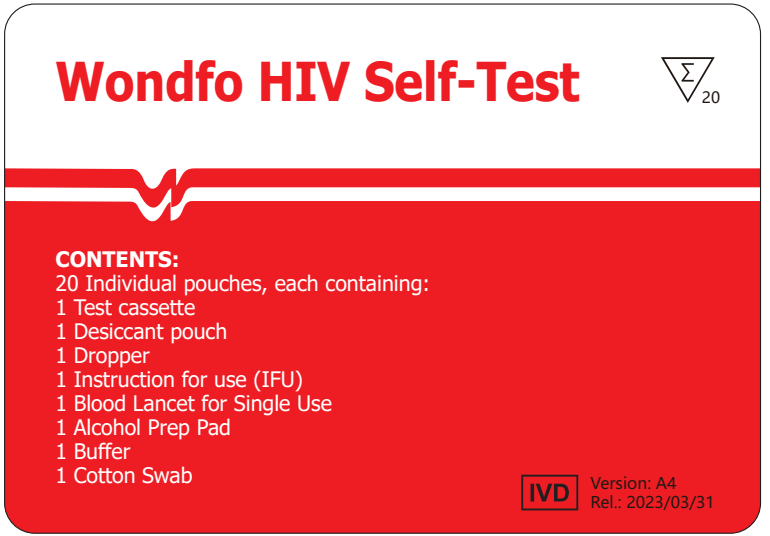
Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.



250 x 185 x 105mm

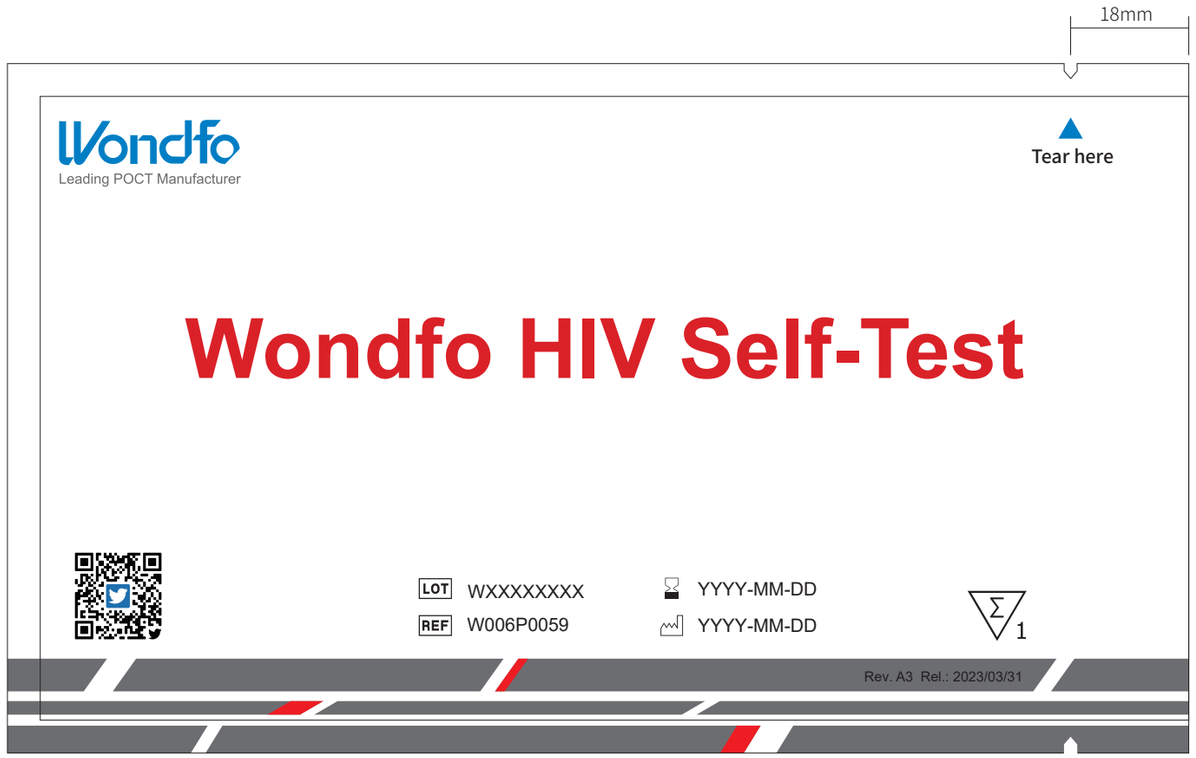
Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.



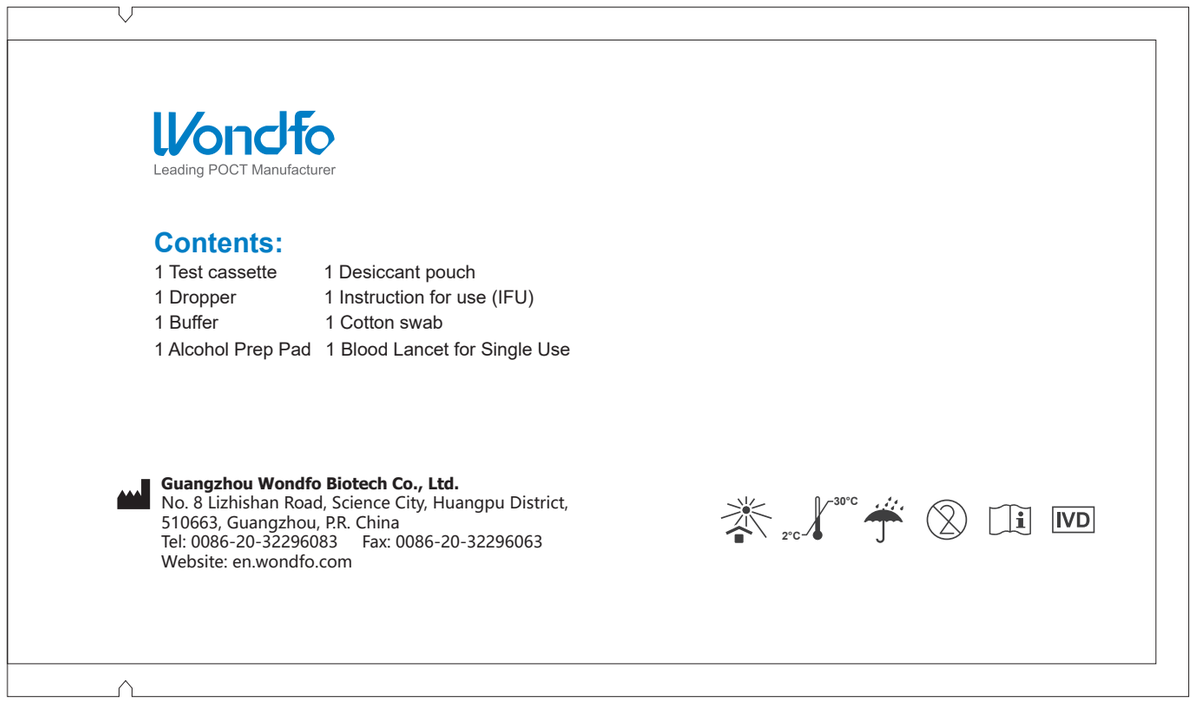


Secondary Packaging Label of W006P0059

Front



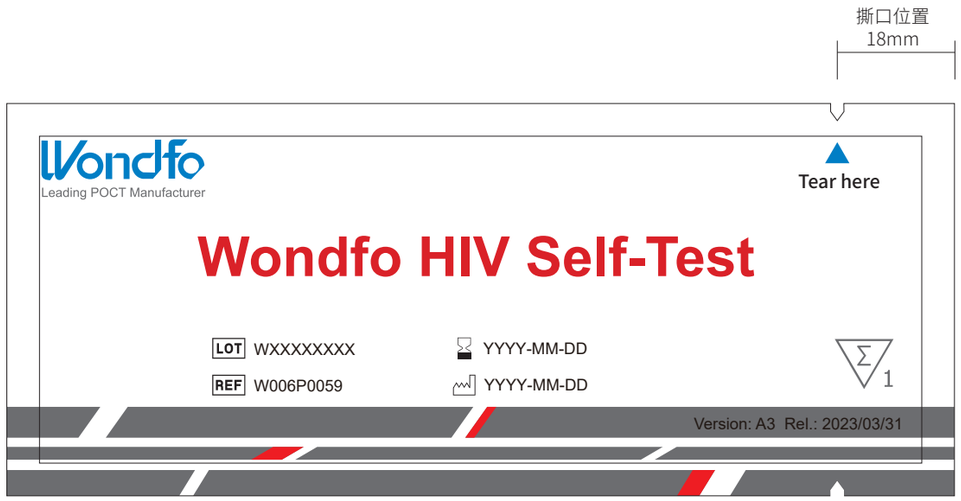
Back



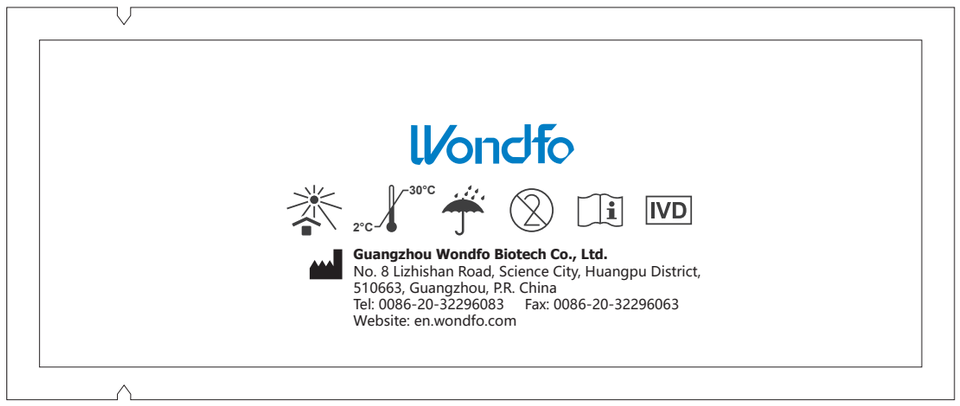
Foil Pouch for W006P0059

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

Front



Back



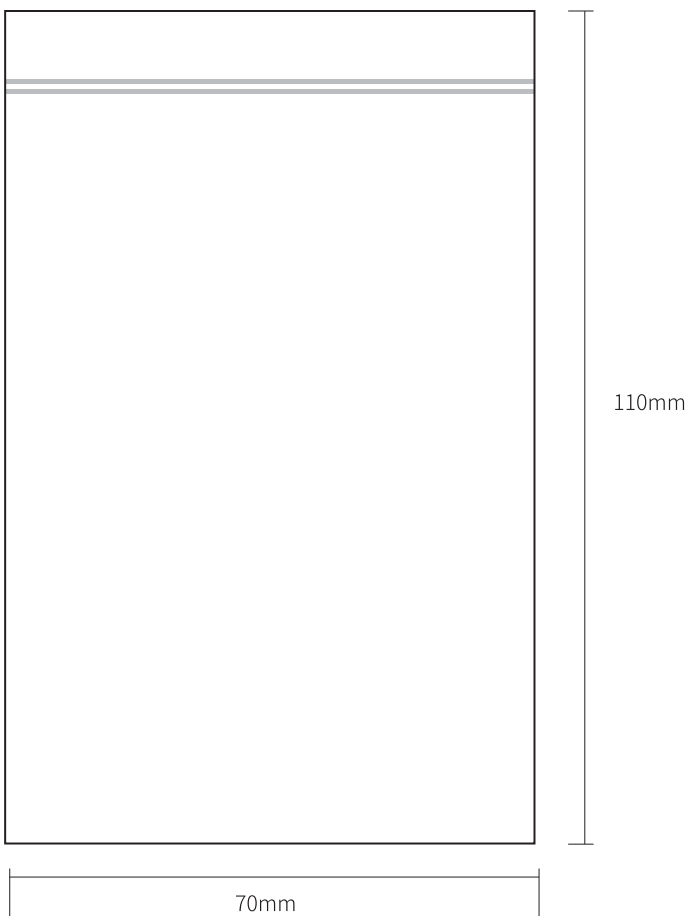
Test Cassette Foil Pouch for W006P0059

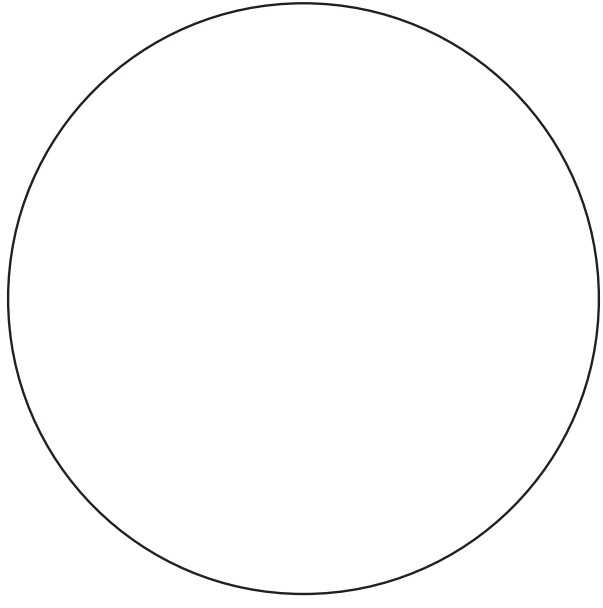
Note: The lot number have three formats. Format 1 is WXXXXXXXXXX which is eleven characters, format 2 is WXXXXXXXXX which is ten characters, and format 3 is WXXXXXXXX which is nine characters.

Front


自封口
10mm
Wondfo
Accessories pouch
CONTENT:
1 Buffer (0.3mL)
1 Dropper
1 Alcohol prep pad
1 Blood Lancet for Single Use
1 Cotton swab
Version: A1
Rel.: 2023/03/31

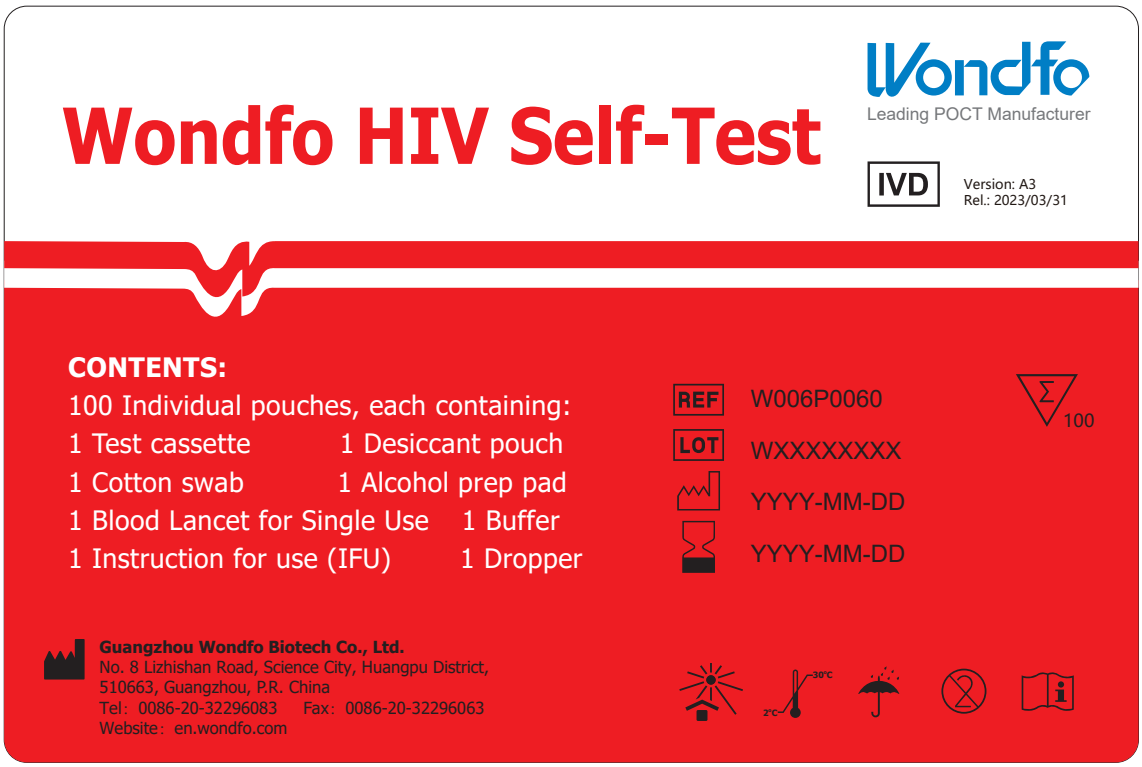
Back


110mm
70mm



Round Sticker

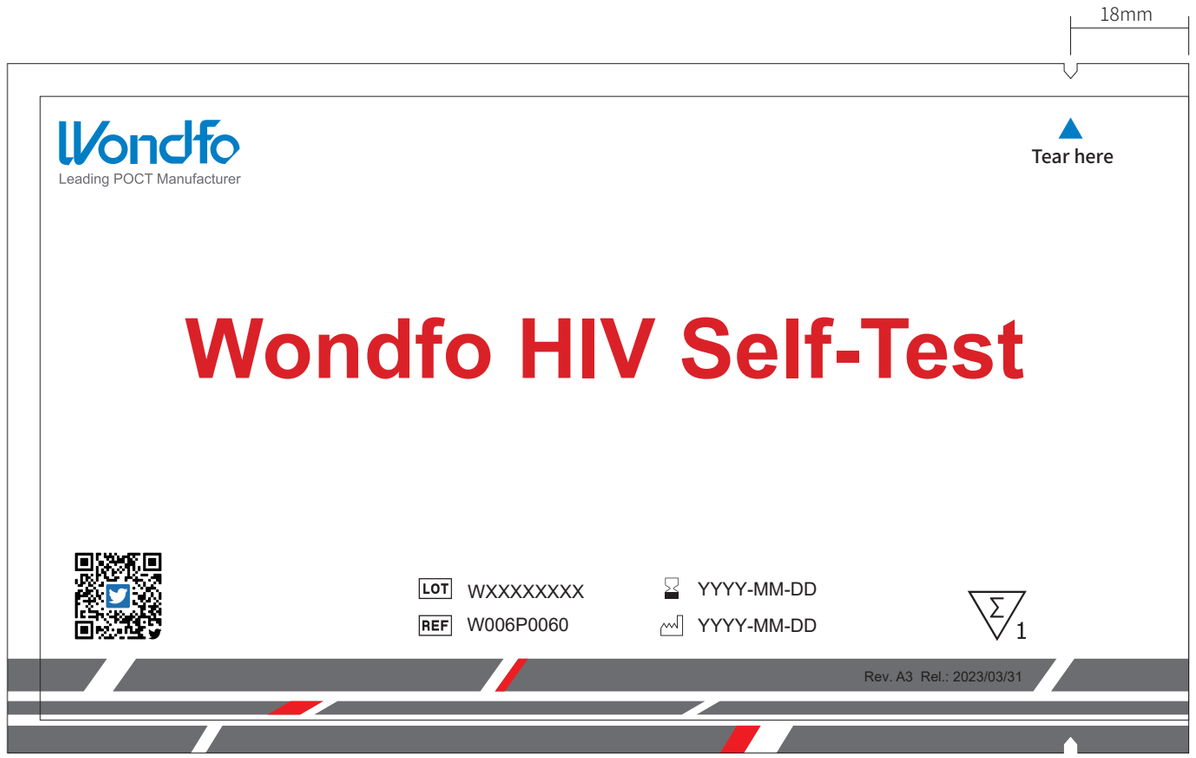
1.3 Labels for product code W006P0060



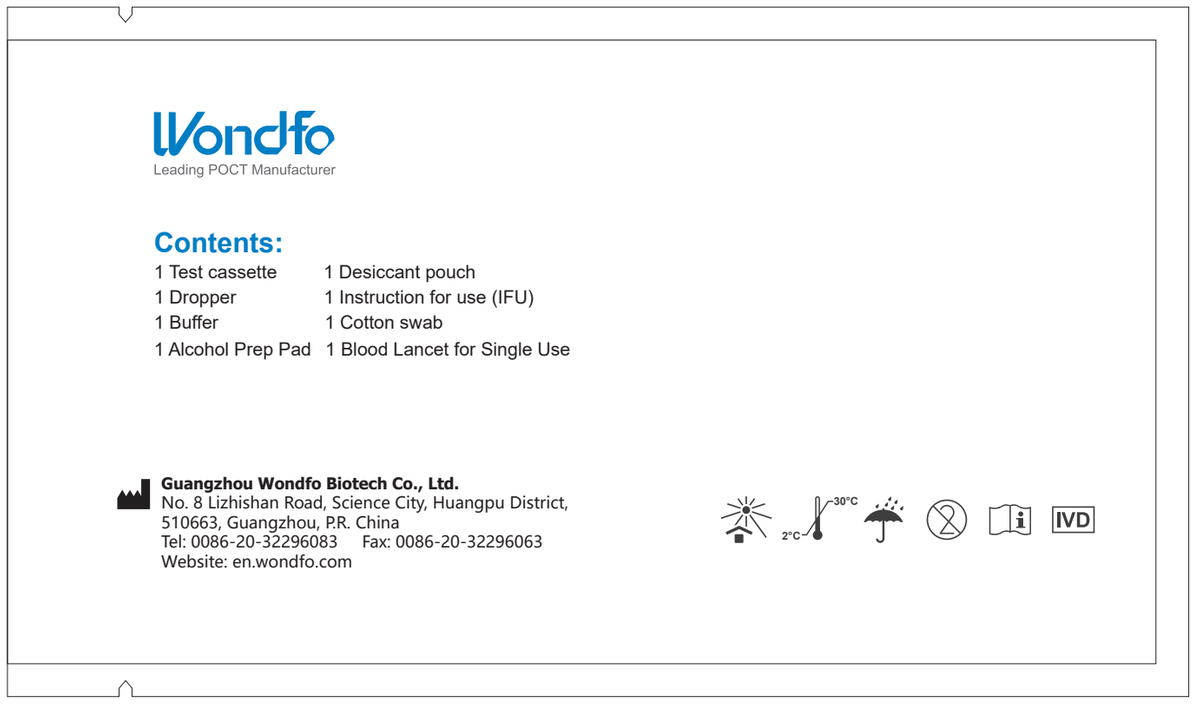
Secondary Packaging Label for W006P0060

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



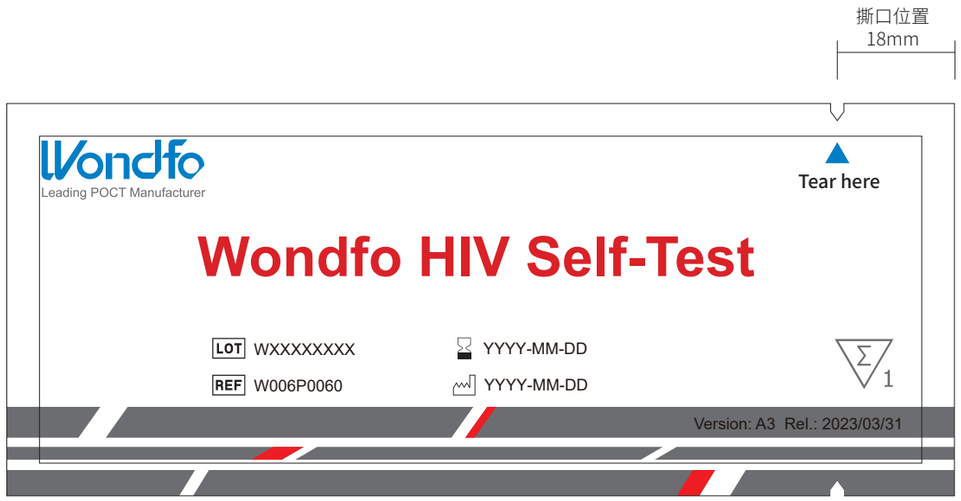
Back



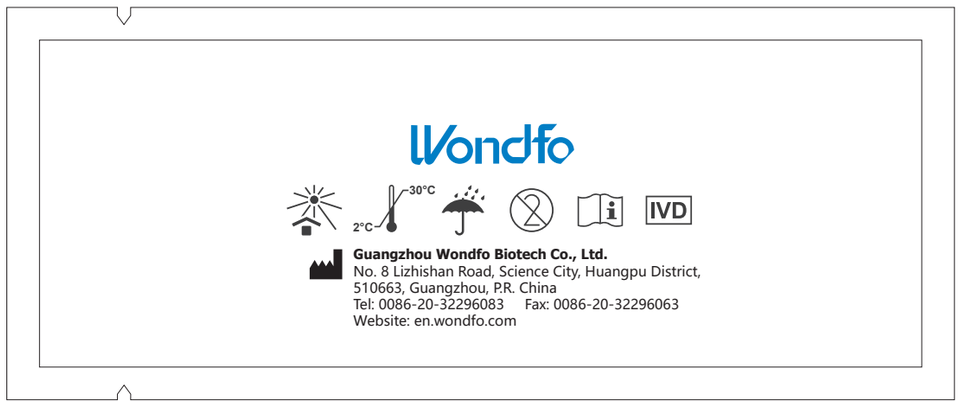
Foil Pouch for W006P0060

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

Front



Back



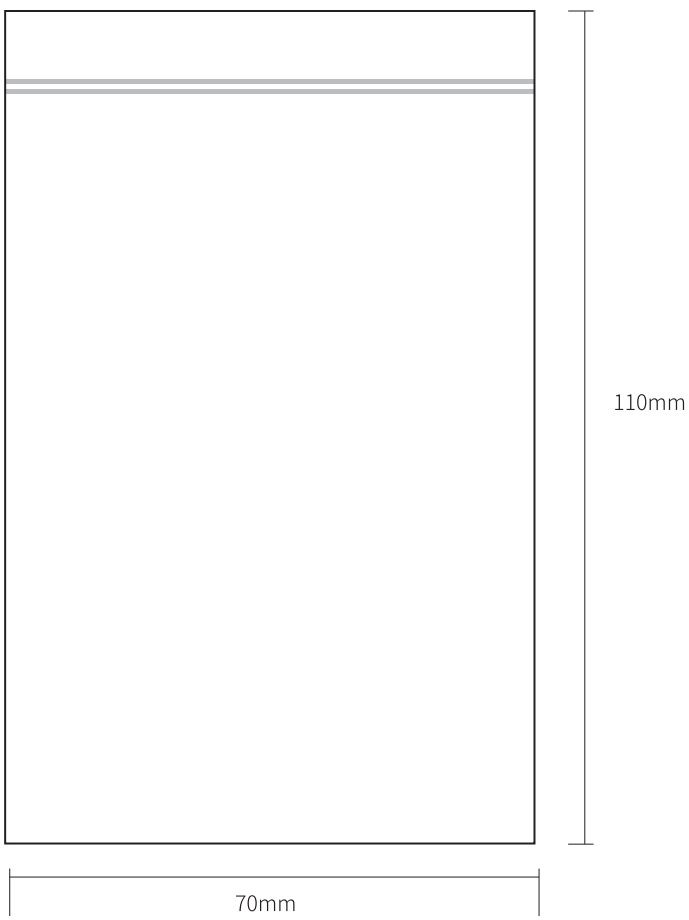
Test Cassette Foil Pouch for W006P0060

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


自封口
10mm
Wondfo
Accessories pouch
CONTENT:
1 Buffer (0.3mL)
1 Dropper
1 Alcohol prep pad
1 Blood Lancet for Single Use
1 Cotton swab
Version: A1
Rel.: 2023/03/31

Back


110mm
70mm

2.0 Instructions for use[3]

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

ENGLISH

Rev. A7 Rel.: 2023/03/31

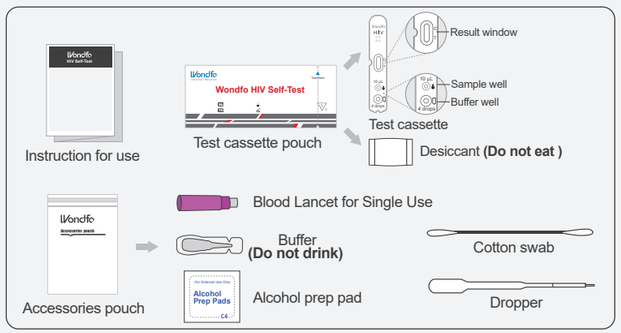
Wondfo HIV Self-Test

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

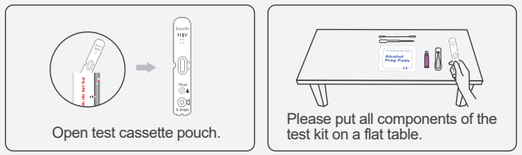
Contents



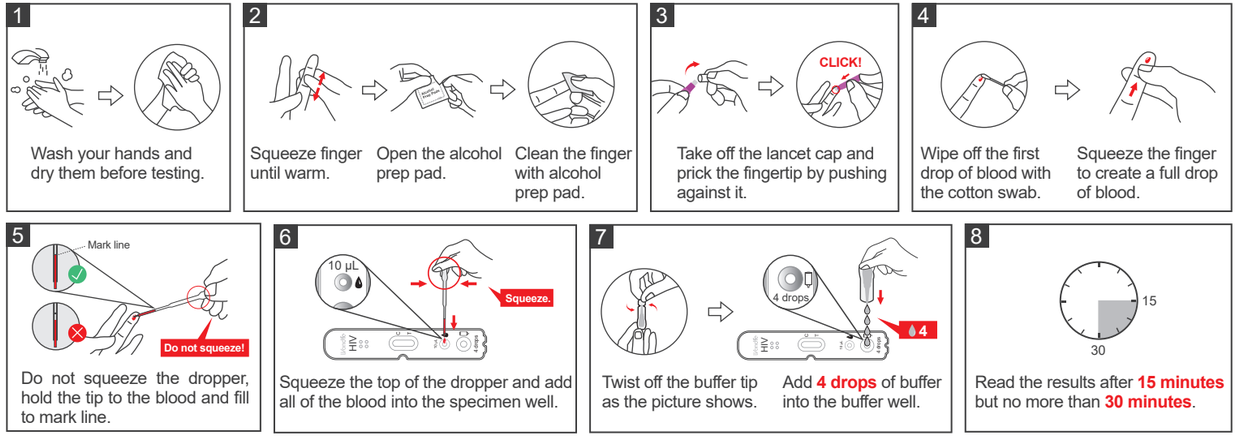
Materials may be required but not provided.

Timer Tissue Bandage

Preparation



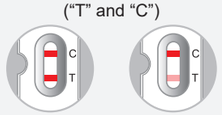
How to use the test kit (for fingerstick whole blood use)



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

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	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.

Add: No.8 Lizhishan Road, Science City, Huangpu 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: en.wondfo.com

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

FRANÇAIS

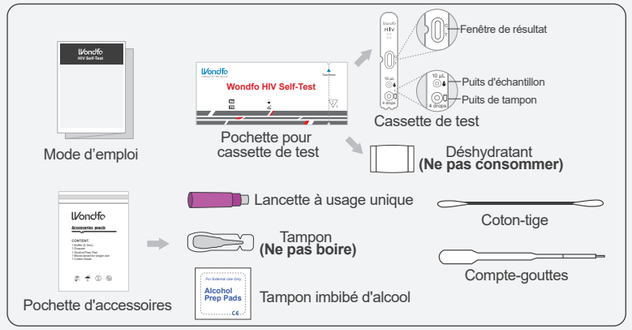
Wondfo HIV Self-Test

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

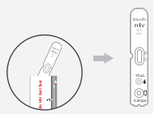
Contenu



Matériel pourrait être requis mais non fourni.

Minuterie | Serviettes en papier | Bandage

Préparation

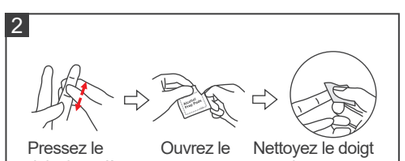


Ouvrez la pochette de la cassette de test.

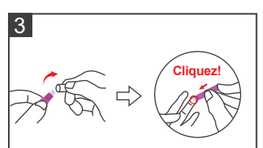
Veuillez placer tous les composants du kit de test sur une table plate.

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

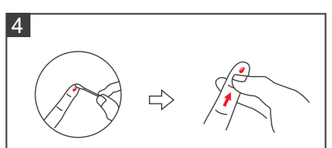
1. Lavez vos mains et séchez-les avant de procéder au test.



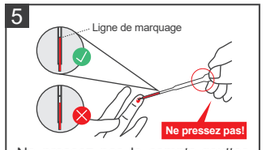
2. Pressez le doigt jusqu'à ce qu'il soit chaud. Ouvrez le tampon imbibé d'alcool. Nettoyez le doigt avec le tampon imbibé d'alcool



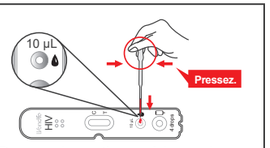
3. Retirez le capuchon de la lancette jetable et piquez le bout du doigt en appuyant dessus.



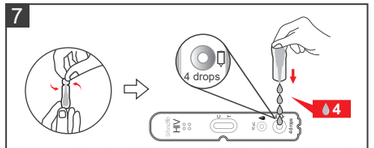
4. Essuyez la première goutte de sang avec un coton-tige. Pressez le doigt pour avoir une goutte de sang suffisante.



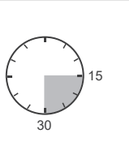
5. Ne pressez pas le compte-gouttes, dirigez l'extrémité du compte-gouttes vers le sang et remplissez-le jusqu'à la ligne de marquage.



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



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

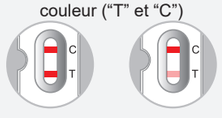


8. Lisez le résultat après **15 minutes** mais pas plus de **30 minutes**.

Comment lire le test

Positif (+)

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



Rendez-vous dans une clinique pour un test de confirmation dès que possible.

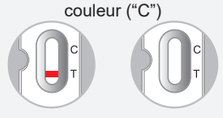
Négatif (-)

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

Refaites un 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 dispensaire le plus proche.

Invalide

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



Effectuez un autre test ou allez dans une clinique pour un test de confirmation.

Élimination

Jetez tous les objets contenus dans la poubelle normale 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 le produits

N° DE CATALOGUE

W006P0058 W006P0059 W006P0060

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 le 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 3 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
Pochette pour cassette de test	Cassette d'essai(pièces)	1	1x20	1x100
	Dessiccant(pièces)	1	1x20	1x100
Accessoires	Compte-gouttes(pièces)	1	1x20	1x100
	Tampon(flacon)	1	1x20	1x100
	Mode d'emploi(pièces)	1	1x20	1x100
	Lancette à usage unique(pièces)	1	1x20	1x100
	Tampon alcoolisé(pièces)	1	1x20	1x100
	Coton-tige(pièces)	1	1x20	1x100
	Sac poubelle(pièces)	1	/	/

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 à 2-30 °C pendant 24 mois.
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 détecter le sang total humain prélevé au bout du 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

Lors d'une étude clinique, 900 participants qui ne connaissaient pas leur statut VIH ont reçu Wondfo HIV Self-Test pour l'autotest. Les résultats ont été comparés à un test de laboratoire de 4e génération. Les résultats de laboratoire montrent qu'au total, 77 participants étaient séropos tives et 822 séronégatives et 1 indéterminé. 43 participants (5 séropositifs, 37 séronégatifs et 1 indéterminé) ont été exclus de l'analyse des performances. La comparaison des résultats a été la suivante :

- 95.8 % des participants (69 sur 72) ont correctement déclaré que leur résultat était positif. Cela signifie que 3 participants infectés par le VIH ont rapporté un résultat de test négatif. C'est ce qu'on appelle un faux négatif.
- 99.6 % des participants (782 sur 785) ont correctement déclaré que leur résultat était négatif. Cela signifie que 3 participants qui n'ont pas été infectés par le VIH ont rapporté un résultat de test positif. C'est ce qu'on appelle un faux positif.
- 4,7% des participants (42 sur 900) n'ont pas réussi à obtenir un résultat de test. Le statut d'infection par le VIH d'un participant n'a pas été confirmé pendant l'étude clinique, il a donc été exclu de l'analyse.

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 limite d'utilisation
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	

Informations sur le fabricant

Guangzhou Wondfo Biotech Co., Ltd.

Add: 8 rue Lizhishan, Cité des Sciences, arrondissement Huangpu, 510663, Guangzhou, République populaire de Chine

Tél: +86-20-32296083 400-888-5268 (appel gratuit)

Fax: +86-20-32296063

E-mail: global@wondfo.com.cn

Site web: en.wondfo.com

Veuillez contacter le fabricant ou votre distributeur local si vous avez des questions concernant le produit.

ENGLISH

Rev. A7 Rel.: 2023/03/31

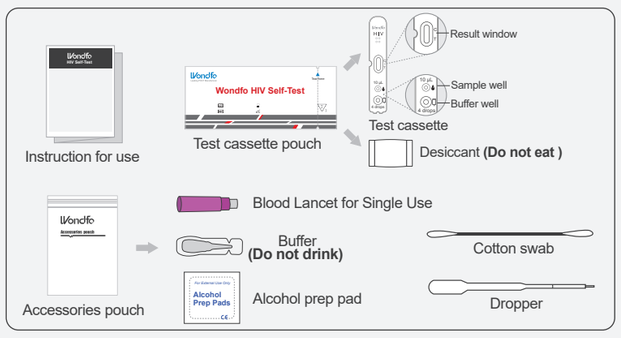
Wondfo HIV Self-Test

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

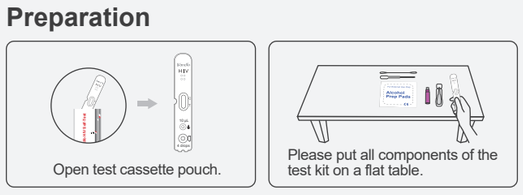
Contents



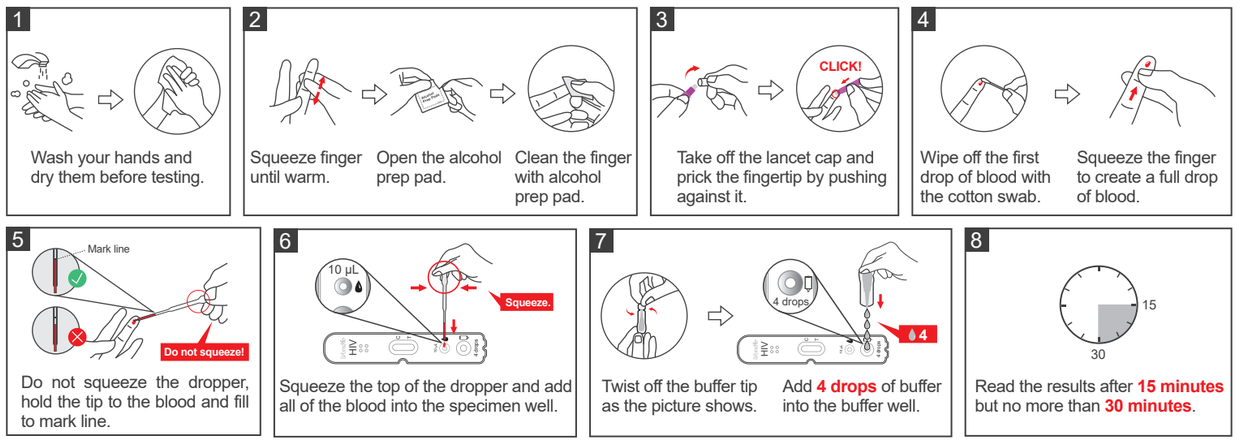
Materials may be required but not provided.

Timer Tissue Bandage

Preparation



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

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	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.

Add: No.8 Lizhishan Road, Science City, Huangpu 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: en.wondfo.com

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

FRANÇAIS

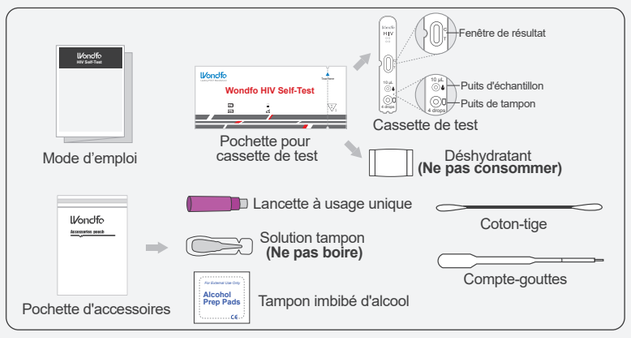
Wondfo HIV Self-Test

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

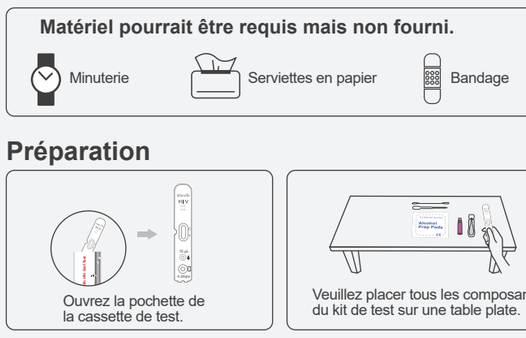
Contenu



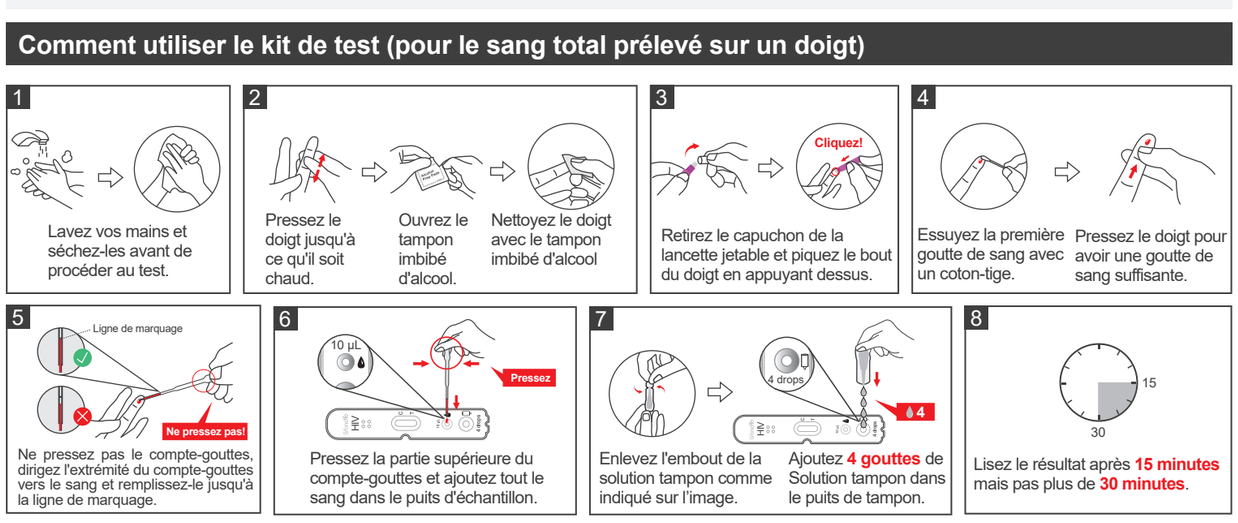
Matériel pourrait être requis mais non fourni.

Minuterie Serviettes en papier Bandage

Préparation



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



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

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 3 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
Pochette pour cassette de test	Cassette d'essai(pièces)	1	1x20	1x100
	Dessiccant(pièces)	1	1x20	1x100
Accessoires	Compte-gouttes(pièces)	1	1x20	1x100
	Solution tampon(flacon)	1	1x20	1x100
	Mode d'emploi(pièces)	1	1x20	1x100
	Lancette à usage unique(pièces)	1	1x20	1x100
	Tampon alcoolisé(pièces)	1	1x20	1x100
	Coton-tige(pièces)	1	1x20	1x100
	Sac poubelle(pièces)	1	/	/

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 à 2-30 °C pendant 24 mois.
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 détecter le sang total humain prélevé au bout du 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

Lors d'une étude clinique, 900 participants qui ne connaissaient pas leur statut VIH ont reçu Wondfo HIV Self-Test pour l'autotest. Les résultats ont été comparés à un test de laboratoire de 4e génération. Les résultats de laboratoire montrent qu'au total, 77 participants étaient séropos tives et 822 séronégatives et 1 indéterminé. 43 participants (5 séropositifs, 37 séronégatifs et 1 indéterminé) ont été exclus de l'analyse des performances. La comparaison des résultats a été la suivante :

- 95.8 % des participants (69 sur 72) ont correctement déclaré que leur résultat était positif. Cela signifie que 3 participants infectés par le VIH ont rapporté un résultat de test négatif. C'est ce qu'on appelle un faux négatif.
- 99.6 % des participants (782 sur 785) ont correctement déclaré que leur résultat était négatif. Cela signifie que 3 participants qui n'ont pas été infectés par le VIH ont rapporté un résultat de test positif. C'est ce qu'on appelle un faux positif.
- 4,7% des participants (42 sur 900) n'ont pas réussi à obtenir un résultat de test. Le statut d'infection par le VIH d'un participant n'a pas été confirmé pendant l'étude clinique, il a donc été exclu de l'analyse.

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 limite d'utilisation
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	

Informations sur le fabricant

Guangzhou Wondfo Biotech Co., Ltd.

Add: 8 rue Lizhishan, Cité des Sciences, arrondissement Huangpu, 510663, Guangzhou, République populaire de Chine
Tél: +86-20-32296083 400-888-5268 (appel gratuit)
Fax: +86-20-32296063
E-mail: global@wondfo.com.cn
Site web: en.wondfo.com

Veuillez contacter le fabricant ou votre distributeur local si vous avez des questions concernant le produit.

PIDGIN

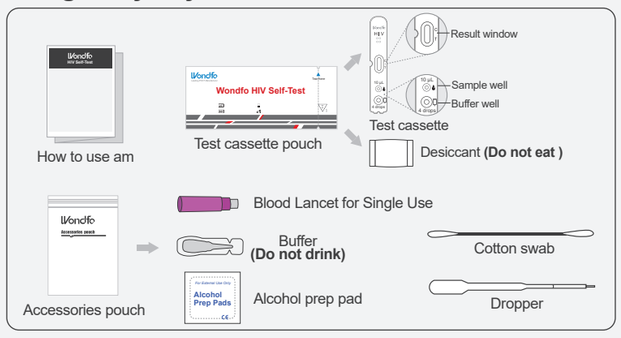
Wondfo HIV Self-Test

How to use am

- You must to follow how dem dey do de test jeje-je to get beta result.
- Siddon for clean place wey get light and make sure say yu get tins wey u need first for de test.
- Na only one-time dem dey use de test. No open am until yu ready do de test.

Watch the operation video

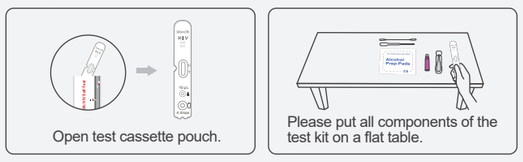
Things way dey inside



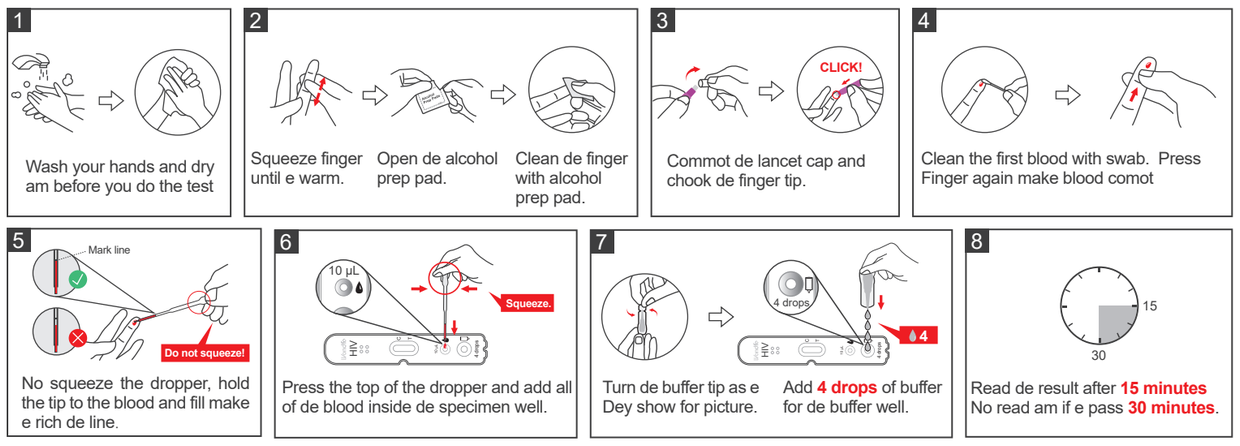
Some things wey yu go need but wey no dey inside.

Timer Tissue Bandage

Preparation



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



How to read the test

Positive (+)

if two color lines show for (“T” and “C”)

Go clinic make dem confam de test sharp sharp.

Negative (-)

If color line no show for (“T”)

Test again in 3 months, if yu don dey expose to HIV or if yu get high risk of infection. Ask dem for hospital how yu fit protect your self.

Invalid

If color bandline no show for (“C”)

Run another test or go clinic make dem confam de test.

DISPOSE

Make yu put all de things wey yu use do test inside dustbin or troway dem how dem dey troway local infectious waste or dustbin wey get blood and other things how government talk am.

Questions and answers

1. Way thing be HIV?

The human immunodeficiency virus (HIV) dey target cells of the immune system, wey dem dey call CD4 cells, wey dey help body fight infection. inside the CD4 cell, HIV dey double come dey damage and destroys the cell. If better treatment of a combination of antiretroviral (ARV) drugs no dey, the immune system no go strong again, and e no go fit fight infection and disease.

2. How dem they transmit HIV?

HIV dey stay for body of people wey get HIV, for blood, semen, vaginal fluids, rectal fluids and breastmilk. HIV dey spread tru:

- When yu collect blood from person wey get HIV.
- When yu use needles, syringes, other injecting equipment, surgical equipment, or things wey sharp wey person don use before.
- From mama wey get belle to pikin wey dey her belle when she dey born or wen she dey give am breast milk.

If person wey get HIV dey take ART (Antiretroviral therapy) medicine well, e go dey kill HIV for body, and e go hard to give another person HIV.

3. Why I suppose test my self?

Person wey don expose to HIV suppose test. de type of test-kit wey dem dey use pass dey see antibodies wey the person produce as part of their immune response to take fight HIV. Plenty times, person body go produce antibodies to HIV within 28 days of infection. For this time person fit see negative wey no be true negative result if dem use antibody test. Person wey dey at risk suppose test sharp sharp, if na negative test result inside 28 days of exposure person suppose still do another test after 3 month to sure of de result.

4. Wetin I suppose do if my result na positive?

Yu go need go hospital make professional person confam am for yu. If dem don confam am, Person for hospital go tell you wetin yu suppose do next.

Product information

CATALOG NO.

W006P0058 W006P0059 W006P0060

INTENDED USE

The Wondfo HIV self-test na to test yoursef for only one time use for invitro diagnostics for fingerstick whole blood detection of HIV-1/2. Dem suppose uase am as self-test and/or by medical professionals.

For *in vitro* diagnostic use only.

PRINCIPLES OF THE PROCEDURE

Wondfo HIV Self-Test dey use double antigen sandwich immunochromatography method. Once yu put blood specimen and the buffer for their respective wells, dem go move along the device by capillary action. The HIV-1 and/or HIV-2 antibodies go join 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 de limit of detection (LOD) of de assay, e produce a visible colored line in the test region (T) and show a positive result. When the levels of HIV-1 or HIV-2 antibodies are zero or below de LOD, no visible colored line go show for the test region (T) showing a negative result. To show say de test kit dey work as an internal procedure control, a colored line go show for de control region (C).

WARNINGS AND CAUTIONS

No use de test kit if expiration date don pass.
No use am if e don burst, tear or e dey open. No test your self if you neva reach 12years.
No use am if you get bleeding problem.
No use am if you already know say u get HIV.
No open the test things if yu neva ready for de test.
Wash your hand and clean am dry before you start the test. The place wey you go do the test must get beta light if you want better result.

Things way they inside

E get 3 configurations of the test kits, 1 test/kit, 20 tests/kit and 100 tests/kit. The things way they inside they listed for down.

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 get: 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).

How to keep am make e no spoil

1. Keep de test kit for store at 2-30 °C for 24 months.
2. Use de test cassette for inside 1 hour after yu open de packet.
3. No keep am for where sunlight, moist and heat dey.
4. Use de kit at 10-30 °C.

LIMITATIONS OF THE PROCEDURE

1. de test na for for detecting human fingerstick whole blood.
2. de test na for qualitative detection of HIV-1 and HIV-2 antibodies.
3. de test assay procedure and result interpretation must be followed well well when testing. For beta test performance, yu must collect blood specimen well well. .if yu no follow how to do am well well, yu no go get beta result.
4. Lie lie results fit happen if:
   - Patients exposed to HIV less than 3 months.
   - Patients dey collect HIV medicine (Antiretroviral therapy).
   - If de number of antibodies of HIV wey dey de blood specimen no reach de amount wey de test go fit see.
5. Lie lie-positive results fit happen if:
   - Patients don do HIV vaccine clinical trial.
6. de colored line wey show for “C” only means say dem add another thing inside the test. It does not guarantee that:
   - de correct blood specimen has been used.
   - de blood specimen has been applied correctly.
7. As all diagnostic tests be, a correct test no be only for result wey yu do one time, but professional healthcare provider also with wetin happen for hospital and de results from other laboratory tests and checkings. No be only results from de Wondfo HIV Self-Test you go use finalize say you don get HIV.

PERFORMANCE CHARACTERISTICS

For de clinical study, dem been give 900 participants wey no know dem HIV status Wondfo HIV Self-Test to test. Dem come compare de results to de 4th generation laboratory test. The laboratory results show say 77 participants be HIV positive, 822 participants be HIV negative and 1 undetermined. 43 of de participants (5 HIV positive, 37 HIV negative and 1 undetermined) been no follow for de performance analysis. de comparison of results be:

- 95.8% of participants (69/72) been correctly report de result as positive. which mean say 3 participants wey get HIV reported negative result. This is called a false negative.
- 99.6% of participants (782/785) been correctly report de result as negative. which mean say 3 participants wey no get HIV reported positive result. This is called a false positive.
- 4.7% of participants (42/900) no get result, 1 participant's HIV infection status no dey confam during de clinical study so e no dey inside de 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	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	No use am if e package dey spoil, and check e instructions for how to use am.	

Manufacturer information

Guangzhou Wondfo Biotech Co., Ltd.

Add: No.8 Lizhishan Road, Science City, Huangpu 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: en.wondfo.com

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

ENGLISH

Rev. A7 Rel.: 2023/03/31

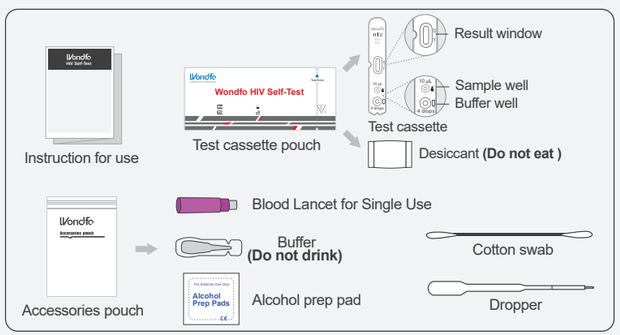
Wondfo HIV Self-Test

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

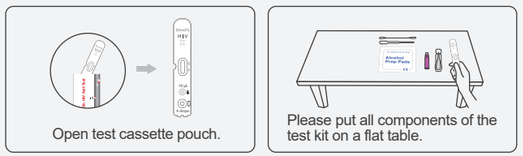
Contents



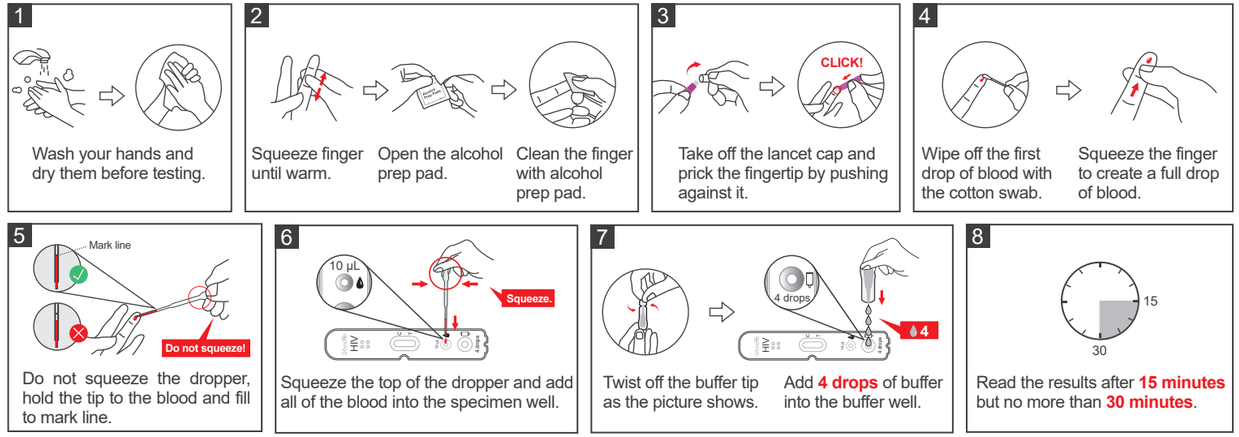
Materials may be required but not provided.

Timer Tissue Bandage

Preparation



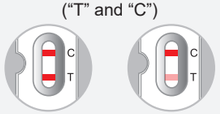
How to use the test kit (for fingerstick whole blood use)



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

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	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.

CHEWA

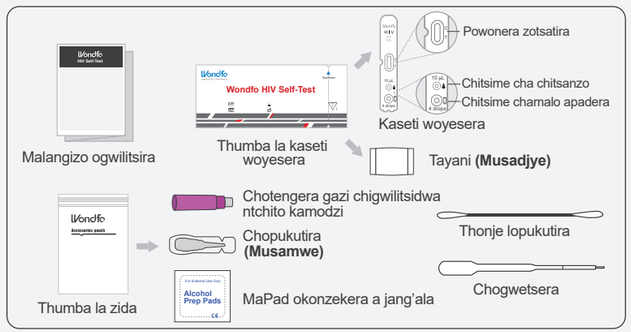
Wondfo HIV Self-Test

Malangizo akugwilitsira ntchito

- Muyenera kutsatira ndondomeko yoyeserera mosamala kuti mupeze zotsatira zolondola
- Khalani pamalo oyera,owala bwino ndipo onetsetsani kuti muli ndi zones musanayambe mayeso.
- Kugwilitsa ntchito kamodzi kokha. Osatsegula thumba la zojambulazo lomwe lili ndi makaseti mpaka mutakonzeka kuyesa.

Onerani kanema wamachitidwe

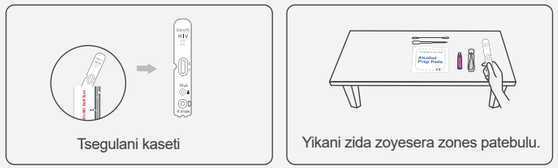
Contenu



Zinthu zitha kufunidwa koma osaperekedwa

Choy Minof Bandeji

Konzekero



Momwe mungagwilitsire ntchito zida zoyesera(kugwilisira ntchito magazi pachala)

Momwe mungawerengere zoyesera

Zabwino (+)

Kupezeka kwa magulu amitundu iwili (“T” ndi “C”)

Pitani kuchipatala kukatsimikizira mayesero mofulumira.

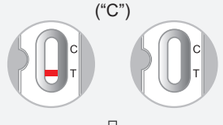
Zoyipa (-)

Palibe kupezeka kwa mtundu (“T”)

Yeseraninso mkati ma miyezi 3 ngati muta lowa pakachilombo kaHIV posachdwa kapena chiwopsvezo chotenga kachilombo. Funsani zopewa HIV pachipatara chapafupi.

Zosavomerezeka

Palibe kupezeka gululamitundu (“C”)



Chitaninso ena mayesero kapena kupita kuchipatara kukatsimikiza ira

Kuthetsa

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.

Mafunso ndi mayankho

1. Kodi HIV ndichiyani?

Kachilombo ka HIV (Human immunodeficiency virus) ndi kachirombo ka HIV komwe kamalimbana ndi maselo a chitetezo cha mthupi, otchedwa CD4 cell, omwe amathandiza thupi kuyankha matenda. Mkati mwa CD4 cell, kachilombo ka HIV kamabwerezabwereza, kenaka, kumawononga maselo. Popanda mankhwala ophatikizika a ma ARV, chitetezo chamthupi chimafooka kwambiri moti sichingathenso kulimbana ndi matenda.

2. Kodi HIV imafalikira bwanji?

Kachilombo ka HIV kamapezeka m'madzi ena am'thupi mwa anthu omwe ali ndi kachilombo ka HIV, kuphatikiza magazi, umuna, ukazi, madzi am'mimba ndi mkaka wa m'mawere. HIV imatha kufalikira ndi:

- Kugonana kosadziteteza kumaliseche, kapena kumatako, komanso nthawi zina kudzera mukugonana m’ kamwa ndi munthu yemwe ali ndi kachilombo ka HIV.
- Kuthilidwa mwazi wamagazi opitsidwa.
- Kugawana singano, majakisoni, zida zina zobaya, zida zopangira opaleshoni kapena zakuthwa
- Kuchokera kwa amayi emwe ali ndi HIV kupita kwa mwana wake wakhanda panthawi yoyembekezera, yobereka kapena yoyamwitsa.

Ngati munthu yemwe ali ndi kachilombo ka HIV akumwa mankhwala a ART (Antiretroviral therapy), omwe amapondereza kwambiri kachilombo ka HIV m’ thupi, mwayi wake wopatsira wina munthu umachepa kwambiri.

3. Ndiyenera kudziyesa lithi?

Anthu omwe ali pachiwopsezo chotenga kachilombo ka HIV kapena omwe ali pachiwopsezo chotenga kachilombo ka HIV ayenera kukayezetsa. Kachilombo ka HIV komwe amagwiritsidwa ntchito kwambiri amapeza ma antibodies opangidwa ndi munthu ngati gawo la chitetezo chawo cholimbana ndi HIV. Nthawi zambiri, anthu amapanga ma antibodies ku HIV pasanathe masiku 28 atadwala. Panthawi imeneyi, anthu amatha kulandira zotsatira zabodza pogwiritsa ntchito antibody test. Ngakhale kuti anthu omwe ali pachiwopsezo chotenga kachilombo ka HIV akuyenera kuyezetsa msanga, zotsatira zake zosonyeza kuti alibe HIV pasanathe masiku 28 atadziwikiratu ziyenera kutsimikiziridwa ndi kuyezetsa kwina pasanathe miyezi itatu.

4. N’ tchite chiyani nditapeza zotsatira zovomeleza?

Muyenera kutsata wazachipatala kuti mukayezetse zina kuti mutsimikizire zotsatira zake. Panthawiyo chipatala cha kwanuko ndi wopereka chithandizo adzakuuzani njira zina zomwe muyenera kuchita.

Mau okhudza za chinthu

CATALOG NO.

W006P0058 W006P0059 W006P0060

ZOFUNIKA KUGWILITSA NTCHITO

Wondfo HIV Self-Test ndi njira imodzi yokha yodziyesera yokha mu vitro yodziyesa kuti muone magazi athunthu a HIV-1/2 ndi chala. Amapangidwa kuti azigwiritsidwa ntchito ngati kudziyesa komanso/kapena ndi akatswiri azachipatala

Kuyang’ anira matenda ndi njira ya *vitro* kokha

MFUNDO YANJIRA YAMACHITIDWE

Wondfo HIV Self-Test amatengera njira ya ma antigen sandwich immunochromatography. Zitsanzo ndi buffer zikawonjezeredwa m'zitsime zomwezo, zimasuntha motsatira chipangizocho ndi capillary action. Ma antibodies a HIV-1 ndi/kapena HIV-2 amamanga ku antigen ya colloidal gold-HIV (gp36/41), ndipo zovutazo zimagwidwa ndi kachilombo ka HIV (gp41 ndi gp36) osasunthika m'chigawo choyesera (T). Pamene milingo ya ma antibodies a HIV-1 kapena HIV-2 ali pamwamba kapena pamwamba pa malire a kudziwika (LOD) ya kuyesa, idzatulutsa gulu lowoneka lachikuda m'chigawo choyesera (T) ndikuwonetsa zotsatira zabwino. Pamene milingo ya ma antibodies a HIV-1 kapena HIV-2 ndi ziro kapena pansi pa LOD, palibe gulu lowoneka bwino m'dera loyezetsa (T) lomwe likuwonetsa zotsatira zoyipa. Kuti ikhale yoyang'anira ndondomeko yamkati, mzere wachikuda udzawonekera pagawo lolamulira (C).

CHENJEZO NDI MALANGIZO

- **Osagwiritsa ntchito** ngati zida zoyeserera zitadutsa tsiku lotha ntchito.
- **Osagwiritsa ntchito** ngati thumba laboola kapena losindikizidwa molakwika.
- **Osagwiritsa ntchito** kudziyesa ngati muli ndi zaka zosakwana 12.
- **Osagwiritsa ntchito** kudziyesa nokha ngati muli ndi vuto lotaya magazi.
- **Osadziyeza ngati** mwapezeka kale ndi kachilombo ka HIV.
- **Osatsegula thumbalo** mpaka mutakonzeka kuyesa.

Sambani m'manja ndipo onetsetsani kuti ali aukhondo ndi owuma musanayambe kuyezetsa. Kuunikira kokwanira kumafunika kuti muwerenge zotsatira za mayeso

CONTENU DU KIT

Pali masanjidwe atatu a zida zoyesera, mayeso amodzi / zida, mayeso 20 / zida ndi 100 mayeso / zida. Zigawo za kit zimaperekedwa monga pansipa:

Zigawo \ No. Ya Ndandanda		W006P0058	W006P0059	W006P0060
Thumba la makaseti oyesera	Kaseti woyesera (pcs)	1	1x20	1x100
	Desiccant (pcs)	1	1x20	1x100
Zida	Chogwetsera (pcs)	1	1x20	1x100
	Mankhwara (vial)	1	1x20	1x100
	IFU (pcs)	1	1x20	1x100
	Chotengera magazi chogwira ntchito kamodzi (pcs)	1	1x20	1x100
	Pad yoyesera yajang’ ala (pcs)	1	1x20	1x100
	Thonje lopukutira (pcs)	1	1x20	1x100
	Disposal bag (pcs)	1	/	/

Mzere umodzi woyesera umaphatikizapo: Mankhwara a Gold conjugate (HIV gp41/gp36 ophatikizidwa ndi antigen ndiponso -gold colloid), Mayeso a(HIV gp41 ndi HIV gp36 yophatikizidwa) ndi Control line (Goat anti rabbit IgG polycloid antibody).

KUSUNGA NDI KUKHAZIKITSIKA

1. Chida choyesera kuchosa kusungidwa pa malo a 2-30 °C kwa miyezi 24.
2. Gwlitsani ntchito kaseti yoyesera mkati ma aura imodzi mutatsegula.
3. Khalitsani kutali ndi kuwala kwa dzuwa, chinyezi ndi kutentha.
4. Gwilitsani ntchito zida zili pa 10-30 °C.

ZOBVUTITSA MACHITIDWE

1. Mayeso adapangidwa kuti azindikire magazi muchala.
2. Kuyezetsako kumangonyangana kuzindikirika kwabwino kwa ma antibodies HIV-1 ndi HIV-2.
3. Njira yoyesera ndi kutanthauzira zotsatira ziyenera kutsatiridwa mosamala poyesa. Kuti mayeso azichita bwino, kusonkhanitsa koyenera ndikofunikira. Kulephera kutsatira ndondomekoyi kungayambitse zotsatira zolakwika
   4.Zotsatira zabodza-zabodza zitha kuchitika mumikhalidwe yotsatirayi:
   - Odwala omwe ali ndi kachilombo ka HIV osakwana miyezi itatu.
   - Odwala omwe ali ndi kachilombo ka HIV (Antiretroviral therapy).
   - Ngati kuchuluka kwa ma antibodies a kachirombo ka HIV kamene kali m'chitsanzo ndi pansi pa mlingo wa kuyeza kwake.
5. Zotsatira zabodza-zabodza zitha kuchitika mumikhalidwe iyi:
   - Odwala omwe ali ndi kachilombo ka HIV osakwana miyezi itatu.
   - Odwala omwe ali ndi kachilombo ka HIV (Antiretroviral therapy).
   - Ngati kuchuluka kwa ma antibodies a HIV omwe ali pachitsanzo ndi otsika kwambiri omwe angadziwike
   - Chitsanzo choyenera chagwilitsidwa ntchito.
   - Chitsanzo chayikidwa bwino-bwino.
6. Mofanana ndi mayesero onse okhudzana ndi matenda, chidziwitso chotsimikizika chachipatala sichiyenera kukhazikitsidwa ndi zotsatira za mayeso amodzi koma m'malo mwake ziyenera kutsimikiziridwa ndi wothandizira zaumoyo mogwirizana ndi zomwe zapezeka m'chipatala komanso zotsatira za mayesero ena a ma laboratory ndi kuunika. Zotsatira zochokera ku Wondfo HIV Self-Test zisagwiritsidwe ntchito ngati maziko okhawo ozindikirira

CARACTÉRISTIQUES DES PERFORMANCES

Mu kafukufuku wachipatala, anthu 900 omwe ali ndi kachilombo ka HIV sankadziwika anapatsidwa Wondfo HIV Self-Test kuti ayese. Zotsatira zinafaniziridwa ndi mayeso a labotale a 4th generation. Zotsatira za labotale zikuwonetsa kuti anthu 77 anali ndi kachilombo ka HIV, 822 analibe kachilombo ndipo m'modzi sanadziwike. Chiwerengero cha anthu 43 (5 omwe ali ndi kachirombo ka HIV, 37 alibe kachirombo ka HIV ndi 1 osadziwika) sanaphatikizidwe pakuwunika ntchito. Kuyerekezera zotsatira kunali motere:

- 95.8% ya anthu (69/72) adanena kuti zotsatira zake zili zabwino. Izi zikutanthauza kuti anthu atatu omwe ali ndi kachilombo ka HIV adanena kuti alibe. Izi zimatchedwa zabodza
- 99.6% mwa anthu (782/785) adanena kuti zotsatira zake zinali zabwino. Izi zikutanthauza kuti anthu atu omwe sanatenge kachilombo ka HIV adanenanso kuti ali ndi HIV. Izi zimatchedwa zabodza
- 4.7% ya ophunzira (42/900) adalephera kupeza zotsatira, 1 kachilombo ka HIV kamene kamakhala ndi kachilombo ka HIV sikunatsimikizidwe panthawi yophunzira zachipatala kotero kuti sichinaphatikizidwe pakuwunika.

MAUMBONI

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.

ZIZINDIKILITSO

IVD Chida chounikira za mankhwalacha *vitro* diagnostic	Malangizo a ntchito	Tsiku lotha ntchito
Σ Kukhala ndi kukwanira kwa < n > tests	Tsiku lakupangidwa	Sungani zouma
LOT Chizindikilitso	Malire akutentha	Sungani kutali ndi kuwala kwa dzuwaKeep
Wopanga	Musagwilitse ntchito kawili	REF Nambala yamalonda
Chenjezo	Ne pas utiliser si l'emballage est endommagé et consulter le mode d'emploi	

TAYANI

Guangzhou Wondfo Biotech Co., Ltd.

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Tel: +86-20-32296083 400-888-5268 (appel gratuit)

Fax: +86-20-32296063

E-mail: global@wondfo.com.cn

Website: en.wondfo.com

Chonde lankhulani ndi wokonza kapena kugulitsa mankhwara amewa ngati mungakhale ndi mafunso pa mankhwara wa .

ENGLISH

Rev. A7 Rel.: 2023/03/31

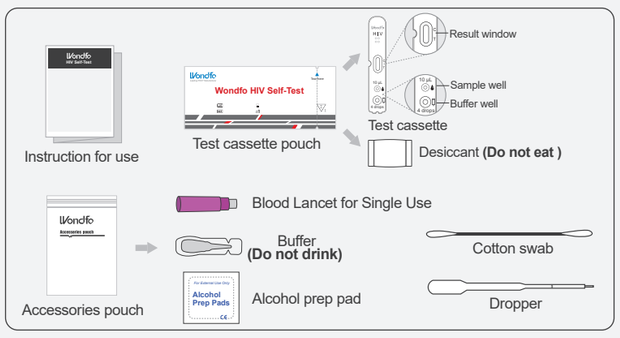
Wondfo HIV Self-Test

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

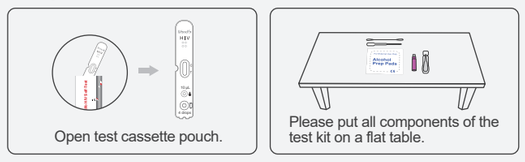
Contents



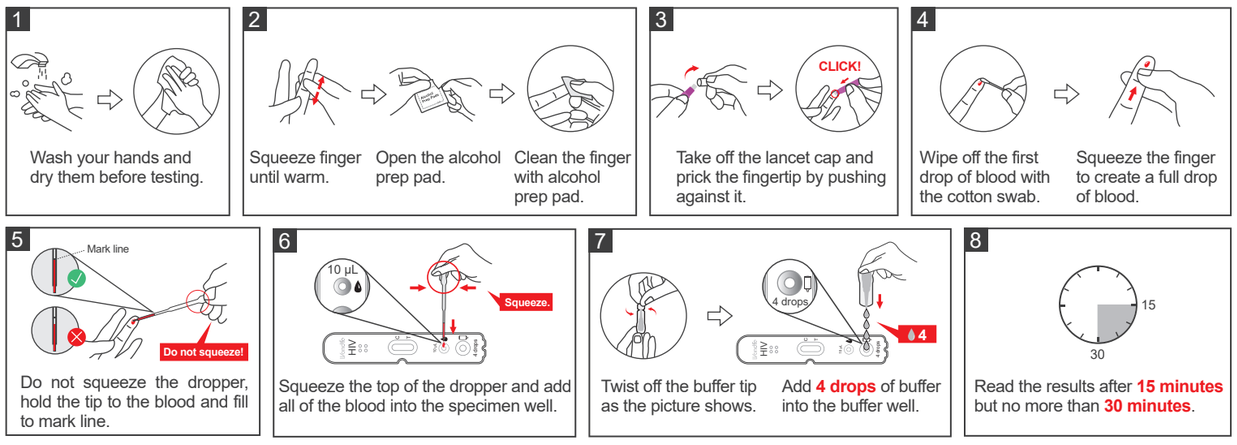
Materials may be required but not provided.

Timer Tissue Bandage

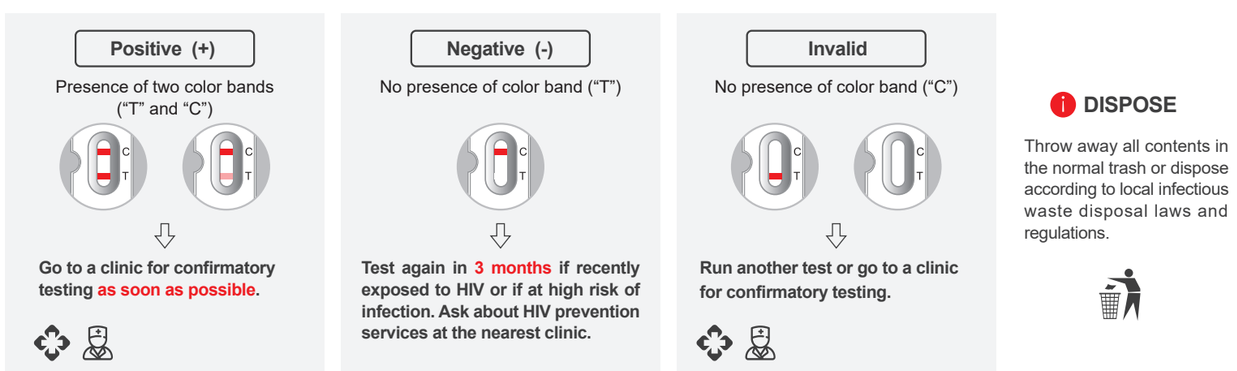
Preparation



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



How to read the test



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

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	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.

Add: No.8 Lizhishan Road, Science City, Huangpu 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: en.wondfo.com

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

FRANÇAIS

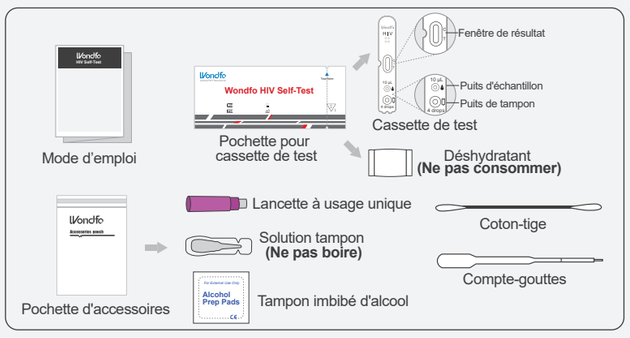
Wondfo HIV Self-Test

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



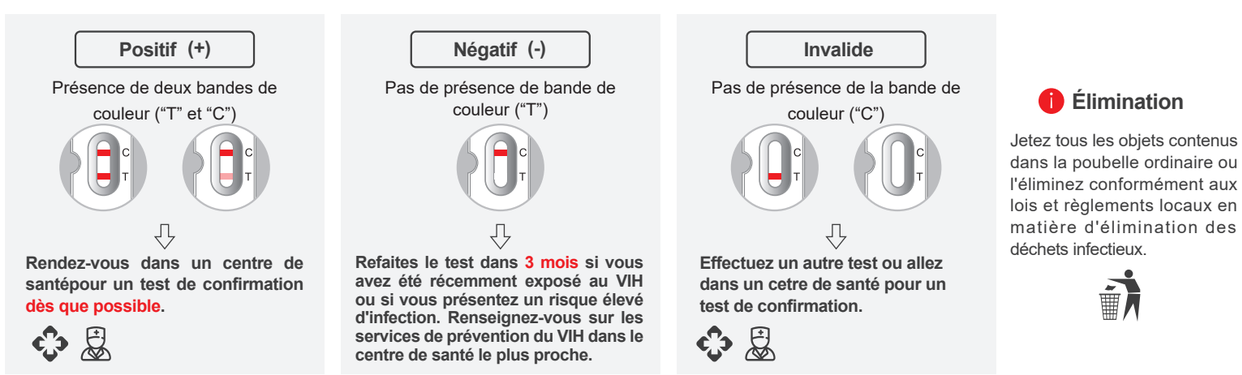
Matériel pourrait être requis mais non fourni.

Minuterie Serviettes en papier Bandage

Préparation

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

Comment lire le test



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

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 3 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
Pochette pour cassette de test	Cassette d'essai(pièces)	1	1x20	1x100
	Dessiccant(pièces)	1	1x20	1x100
Accessoires	Compte-gouttes(pièces)	1	1x20	1x100
	Solution tampon(flacon)	1	1x20	1x100
	Mode d'emploi(pièces)	1	1x20	1x100
	Lancette à usage unique(pièces)	1	1x20	1x100
	Tampon alcoolisé(pièces)	1	1x20	1x100
	Coton-tige(pièces)	1	1x20	1x100
	Sac poubelle(pièces)	1	/	/

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 à 2-30 °C pendant 24 mois.
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 détecter le sang total humain prélevé au bout du 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

Lors d'une étude clinique, 900 participants qui ne connaissaient pas leur statut VIH ont reçu Wondfo HIV Self-Test pour l'autotest. Les résultats ont été comparés à un test de laboratoire de 4e génération. Les résultats de laboratoire montrent qu'au total, 77 participants étaient séropos tives et 822 séronégatives et 1 indéterminé. 43 participants (5 séropositifs, 37 séronégatifs et 1 indéterminé) ont été exclus de l'analyse des performances. La comparaison des résultats a été la suivante :

- 95.8 % des participants (69 sur 72) ont correctement déclaré que leur résultat était positif. Cela signifie que 3 participants infectés par le VIH ont rapporté un résultat de test négatif. C'est ce qu'on appelle un faux négatif.
- 99.6 % des participants (782 sur 785) ont correctement déclaré que leur résultat était négatif. Cela signifie que 3 participants qui n'ont pas été infectés par le VIH ont rapporté un résultat de test positif. C'est ce qu'on appelle un faux positif.
- 4,7% des participants (42 sur 900) n'ont pas réussi à obtenir un résultat de test. Le statut d'infection par le VIH d'un participant n'a pas été confirmé pendant l'étude clinique, il a donc été exclu de l'analyse.

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	

Informations sur le fabricant

Guangzhou Wondfo Biotech Co., Ltd.

Add: 8 rue Lizhishan, Cité des Sciences, arrondissement Huangpu, 510663, Guangzhou, République populaire de Chine
Tél: +86-20-32296083 400-888-5268 (appel gratuit)
Fax: +86-20-32296063
E-mail: global@wondfo.com.cn
Site web: en.wondfo.com

Veuillez contacter le fabricant ou votre distributeur local si vous avez des questions concernant le produit.

SWAHILI

Wondfo

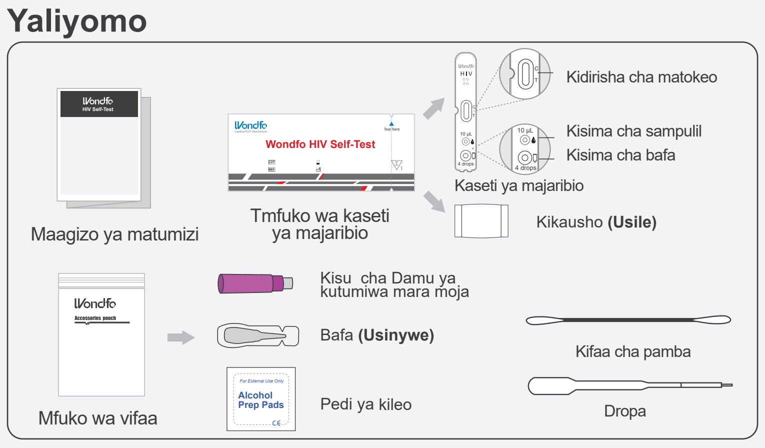
Mpango wa Kujipimia VVU wa Wondfo

Maagizo ya matumizi

- Lazima ufuate utaratibu wa majaribio kwa uangalifu ili kupata matokeo sahihi.
- Keti katika eneo safi, lenye mwanga wa kutosha na uhakikishe kuwa una vitu vyote kabla ya kuanza jaribio.
- Kwa matumizi moja tu. Usifungue kifuko ya karatasi iliyo na kaseti hadi tayari kufanya majaribio.

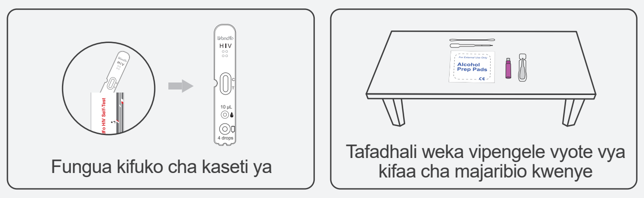
Tazama video ya kutekelezea

Yaliyomo

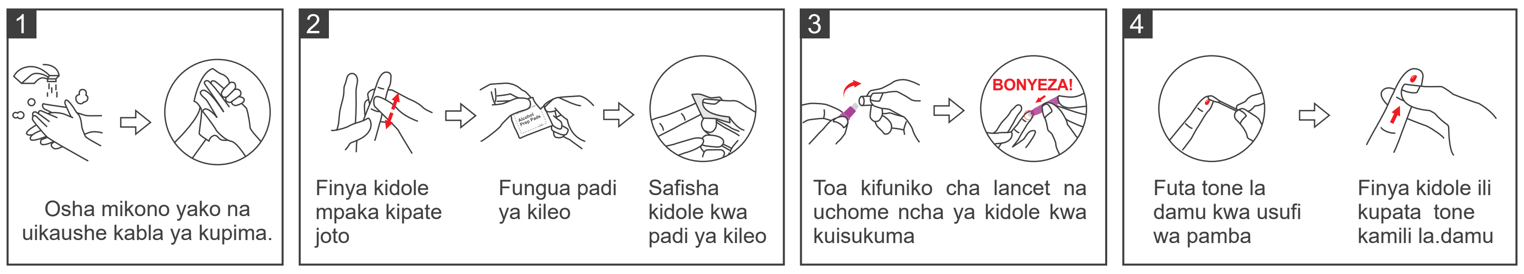


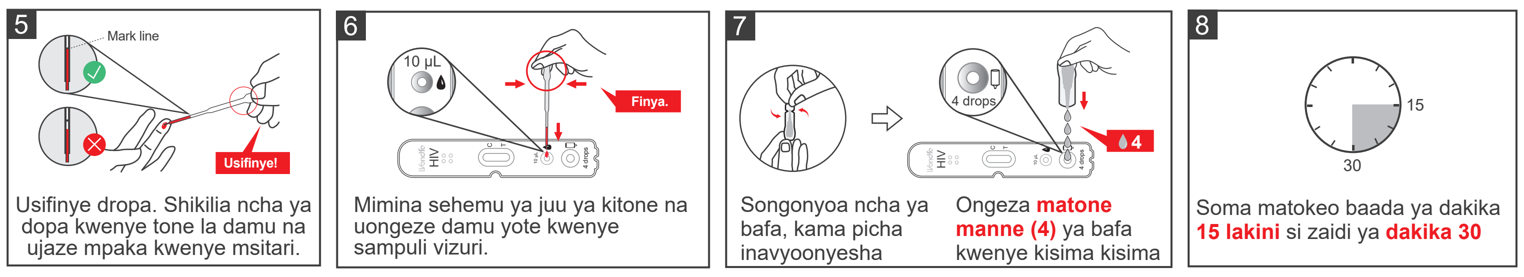
Nyenzo zinaweza kuhitajika lakini hazijatolewa.

Maandalizi

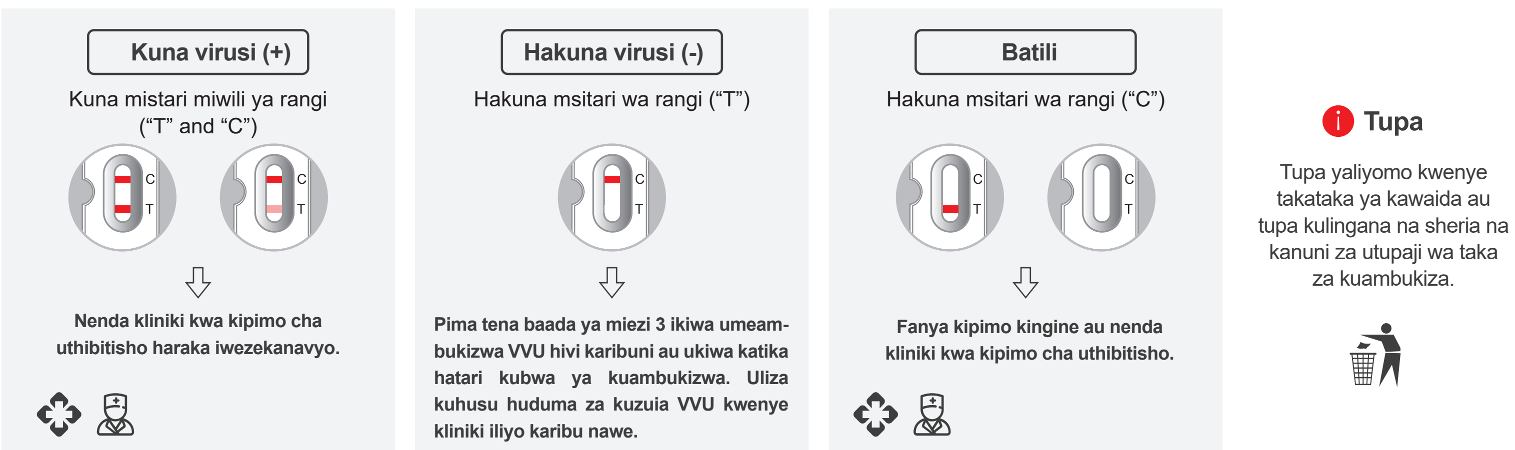


Jinsi ya kutumia kifaa cha majaribio (kupima damu yote kwa kutumia kidole)





Jinsi ya kuelewa matokeo ya majaribio



Maswali na majibu

1. VVU ni nini?

Virusi vya Ukimwi (VVU) hulenga seli za mfumo wa kinga, ziitwazo seli za CD4, ambazo husaidia mwili kukabiliana na maambukizi. Ndani ya seli ya CD4, VVU hujirudufisha na hivyo huharibu seli. Bila matibabu madhubuti ya mchanganyiko wa dawa za kurefusha maisha (ARV), mfumo wa kinga utadhoofika kiasi kwamba hauwezi tena kupambana na maambukizi na magonjwa.

2. VVU huambukizwa vipi?

VVU hupatikana katika giligili fulani za miili ya watu wanaoishi na VVU, mkiwemo damu, shahawa, giligili za ukeni, giligili za rektamu na maziwa ya mama. VVU vinaweza kuambukizwa kwa njia zifuatazo:

- Ngono ya uke au ya mkundu bila kinga, na, katika hali nadra sana, kupitia ngono ya mdomo na mtu anayeishi na VVU.
- Kuongezewa damu yenye VVU.
- Kushiriki sindano, vifaa vingine vya kujidunga, vifaa vya upasuaji au ala zingine zenye ncha kali.
- Kutoka kwa mama anayeishi na VVU hadi kwa mtoto wake mchanga wakati wa ujauzito, kujifungua au kunyonyesha.

Ikiwa mtu anayeishi na VVU anatumia ART (matibabu ya kurefusha maisha), ambayo hukandamiza VVU mwilini, uwezekano wa kusambaza VVU kwa mtu mwingine hupunguzwa sana.

3. Ni lini ninahitaji kujipima?

Watu ambao wameambukizwa VVU au walio katika hatari ya VVU wanapaswa kutafuta kupima. Vipimo vingi vya uchunguzi wa VVU vinavyotumika sana hugundua kingamwili zinazozalishwa na mtu kama sehemu ya mwitikio wa kinga ya mwili wake kupambana na VVU. Mara nyingi, watu hutengeneza kingamwili kwa VVU ndani ya siku 28 baada ya kuambukizwa. Wakati huu, watu wanaweza kupokea matokeo hasi yasiyo sahihi kwa kutumia kipimo cha kingamwili. Ingawa watu walio katika hatari ya kuambukizwa VVU wanapaswa kupima haraka iwezekanavyo, matokeo hasi ya kupima ndani ya siku 28 baada ya kuambukizwa yanapaswa kuthibitishwa na upimaji wa ziada, katika muda usiozidi miezi mitatu baadaye.

4. Nifanye nini nikipata nina VVU?

Unahitaji kufuatilia na mhudumu wa afya ili kupata upimaji wa ziada ili kuthibitisha matokeo. Wakati huo kliniki ya eneo lako na mtoa huduma watapendekeza hatua zinazofuata zinazohitajika kuchukuliwa.

Maelezo kuhusu bidhaa

NA. YA KATALOGI

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MATUMIZI YALIYOKUSUDIWA

Kipimo cha VVU cha Wondfo ni kipimo cha sampuli zilizotolwa mwilini cha mara moja tu cha kugundua VVU-1/2 kwa kutumia vidole. Inakusudiwa kutumiwa kujipima na/au kipimo kikifanywa na wataalamu wa matibabu.

Kwa matumizi ya uchunguzi wa sampuli zilizotolewa mwilini pekee.

KANUNI ZA UTARATIBU

Kipimo cha VVU cha Wondfo kinatumia mara mbili mbinu ya antijeni ya kudondosha sampuli ya kipimo kwenye kifaa cha kupimia. Baada ya sampuli na bafa kuongezwa kwenye visima husika, vitahamia kwenye kifaa kwa njia ya kapilari. Kingamwili za VVU-1 na/au VVU-2 hujiganda kwenye antijeni ya VVU ya colloidal (gp36/41), na mchangamanyo huo kisha kunaswa na antijeni ya VVU (gp41 na gp36) isiyoweza kusonga katika eneo la majaribio (T). Wakati viwango vya kingamwili vya VVU-1 au VVU-2 viko kwenye au juu ya kikomo cha kugunduliwa (LOD) cha kipimo, vitatoa bendi ya rangi inayoonekana katika eneo la jaribio (T) na inaonyesha matokeo chanya. Wakati viwango vya kingamwili za VVU-1 au VVU-2 ni sifuri au chini ya LOD, hakuna bendi ya rangi inayoonekana katika eneo la majaribio (T) kitu kinachoonyesha matokeo hasi. Ili kutumika kama udhibiti wa ndani wa utaratibu, mstari wa rangi utaonekana kwenye eneo la udhibiti (C).

Kipande kimoja cha kupimia kinakuwa na dutu la antijeni la muungano aina ya "Gold conjugate (HIV gp41/gp36 fusion recombinant antigen-gold colloid" pamoja na msitari wa kipimo wa "rabbit IgG polyclonal antibody-gold colloid), Test line (HIV gp41 recombinant antigen and HIV gp36 recombinant antigen) na Msitari wa udhibiti (Goat anti rabbit IgG polyclonal antibody).

ONYO NA TAHADHARI

Usitumie ikiwa ni baada ya tarehe ya mwisho wa matumizi kwenye mfuko wa zana za kipimo.
Usitumie ikiwa kifuko imechomwa au imefungwa vibaya.
Usitumie kujipima ikiwa una umri wa chini ya miaka 12.
Usitumie kujipima ikiwa una ugonjwa wa kutokwa na damu.
Usitumie kujipima ikiwa tayari umegunduliwa kuwa na VVU.
Usitumiekifuko hadi uwe tayari kufanya kipimo.
Osha mikono yako na uhakikishe kuwa ni safi na kavu kabla ya kuanza kupima.
Mwanga wa kutosha unahitajika ili kutazama matokeo ya kipimo.

YALIYOMO NDANI YA KIFUKO

Kuna usanidi wa aina 3 wa vifaa vya kupimia, jkipimo/kifuko 1, vipimo/vifuko 20 na vipimo/vifuko 100. Yaliyomo kwenye kifuko yanatolewa kama ifuatavyo:

Components	Catalog No.	W006P0058	W006P0059	W006P0060
Mfuko wa kaseti ya vipimo	Kaseti za vipimo	1	1x20	1x100
	Vikausho	1	1x20	1x100
Vifaa	Dropa	1	1x20	1x100
	Bafa (kichupa kidogo)	1	1x20	1x100
	Maaagizo ya Matumizi	1	1x20	1x100
	Vifaa ya kutoa sampuli ya damu vya kutumia mara moja tu	1	1x20	1x100
	Padi zenye kileo	1	1x20	1x100
	Usufi wa pamba	1	1x20	1x100
	Mfuko wa kutupia	1	/	/

HIFADHI NA UTULIVU

1. Kifuko ya vifaa inaweza kuhifadhiwa katika joto la 2-30 ° C kwa miezi 24.
2. Tumia kaseti ya kipimo ndani ya saa 1 baada ya kufungua kifuko.
3. Weka mbali na jua, unyevu na joto.
4. Tumia vifaa katika joto la 10-30 °C.

MAPUNGUFU YA UTARATIBUU

1. Kipimo kimetengenezwa kwa ajili ya kuchunguza damu nzima ya binadamu kwa kutumia kidole.
2. Kipimo kimetengenezewa tu ugunduzi wa kingamwili za VVU-1 na VVU-2 zilizomo.
3. Utaratibu wa upimaji na fasiri ya matokeo unafaa kufuatwa kwa karibu wakati wa kupima. Kwa utendakazi bora wa kipimo, ni muhimu kuhakikisha ukukusanyaji sahihi wa sampuli. Kukosa kufuata utaratibu kunaweza kusababisha matokeo ya kipimo yasiyo sahihi.
4. Matokeo hasi ya uwongo yanaweza kutokea katika hali zifuatazo:
   - Wagonjwa walioambukizwa VVU chini ya miezi 3.
   - Wagonjwa wanaopata matibabu ya VVU (Antiretroviral therapy).
   - Iwapo idadi ya kingamwili za VVU iliyomo kwenye sampuli iko chini ya kiwango cha ugunduzi cha kipimo.
5. Matokeo chanya ya uwongo yanaweza kutokea katika hali zifuatazo:
   - Wagonjwa wameshiriki katika jaribio la kimatibabu la chanjo ya VVU.
6. Uwepo wa mstari wa udhibiti unamaanisha tu kwamba uhamiaji wa kioevu kilichoongezwa ulitokea. Haina uhakika kwamba:
   - Sampuli sahihi imetumika.
   - Sampuli imetumika kwa usahihi.
7. Kama ilivyo kwa vipimo vyote vya uchunguzi, utambuzi wa uhakika wa kipimo haupaswi kutegemea matokeo ya kipimo kimoja bali unapaswa kuamuliwa na mhudumu wa afya pamoja na matokeo ya kimatibabu na matokeo ya vipimo na tathmini nyinginezo za kimaabara. Matokeo kutokana na Kujipima VVU kwa Wondfo hayapaswi kutumiwa kama msingi pekee wa utambuzi wa VVU.

TABIA ZA UTENDAJI

Katika utafiti wa kimatibabu, washiriki 900 ambao hali yao ya VVU haikujulikana walipewa Kipimo cha VVU cha Wondfo ili kupima. Matokeo ya kipimo hicho yalilinganishwa na kipimo cha maabara cha ngazi ya 4. Matokeo ya maabara yalionyesha kuwa jumla ya washiriki 77 walikuwa na VVU, washiriki 822 hawakuwa na VVU na hali ya mshiriki 1 haikutambuliwa. Jumla ya washiriki 43 (5 wana VVU, 37 hawana VVU na 1 hali haikuamuliwa) hawakujumuishwa katika uchambuzi wa utendaji. Ulinganisho wa matokeo ulikuwa kama ifuatavyo:

- Asilimia 95.8 ya washiriki (69/72) waliripoti kwa usahihi matokeo kuwa chanya. Hii ina maana kwamba washiriki 3 walioambukizwa VVU waliripoti matokeo hasi. Hii inaitwa hasi isiyo sahihi.
- Asilimia 99.6 ya washiriki (782/785) waliripoti kwa usahihi matokeo kuwa hasi. Hii ina maana kwamba washiriki 3 ambao hawajaambukizwa VVU waliripoti matokeo chanya. Hii inaitwa chanya cha isiyo sahihi.
- Asilimia 4.7 ya washiriki (42/900) walishindwa kupata matokeo, hali ya maambukizi ya VVU ya mshiriki 1 haikuthibitishwa katika uchunguzi wa kimatibabu; kwa hivyo haikujumuishwa kwenye uchambuzi.

MAREJELEO

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.

MAELEZO YA ISHARA

IVD	In vitro diagnostic medical device		Consult instructions for use		Use-by date
Σ	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	Product code/ Catalogue number
	Caution		Usitumie ikiwa kifurushi kimeharibishwa na shauriana na maagizo ya matumizi		

Taarifa za mtengenezaji

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Tovuti: en.wondfo.com

Tafadhali wasiliana na mtengenezaji au msambazaji waeneo lako ikiwa una maswali yoyote kuhusiana na bidhaa.

Amharic

Wondfo

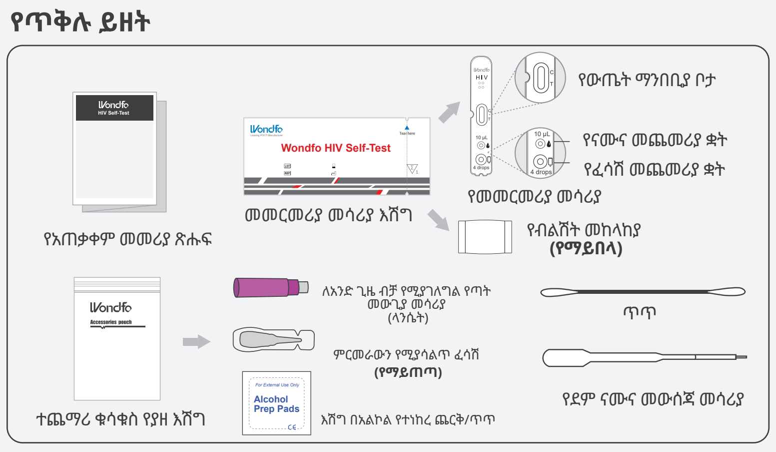
የወንድፎ ራስን (በራስ) የኤች. አይ.ቪ . መመርመሪያ

የአጠቃቀም መመሪያ

- [illegible]
- [illegible]
- [illegible]

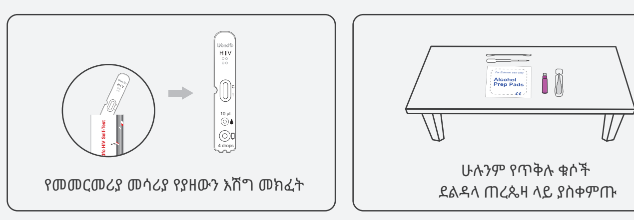
አሠራሩን የሚያሳየውን ቪዲዮ ይመልከቱ

የጥቅሉ ይዘት

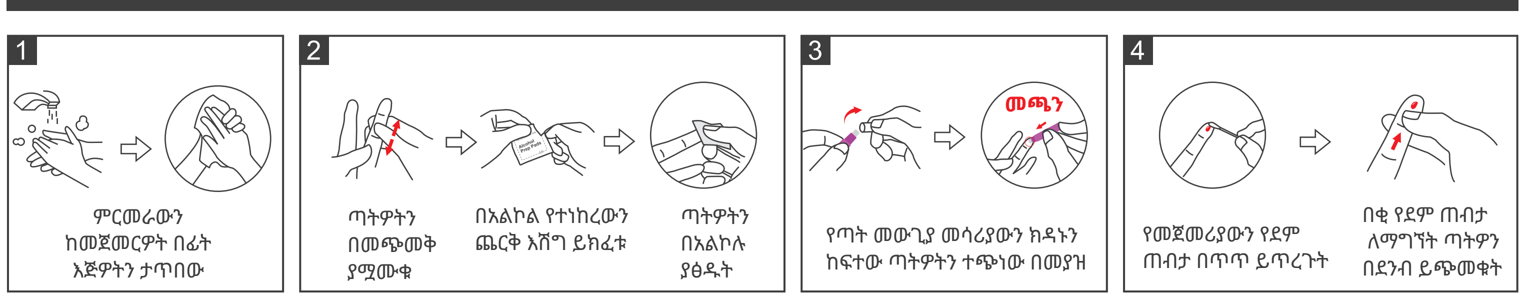


አስፈላጊ የሆኑ ግን ጥቅሉ ውስጥ ያልተካተቱ ቁሳቁስ

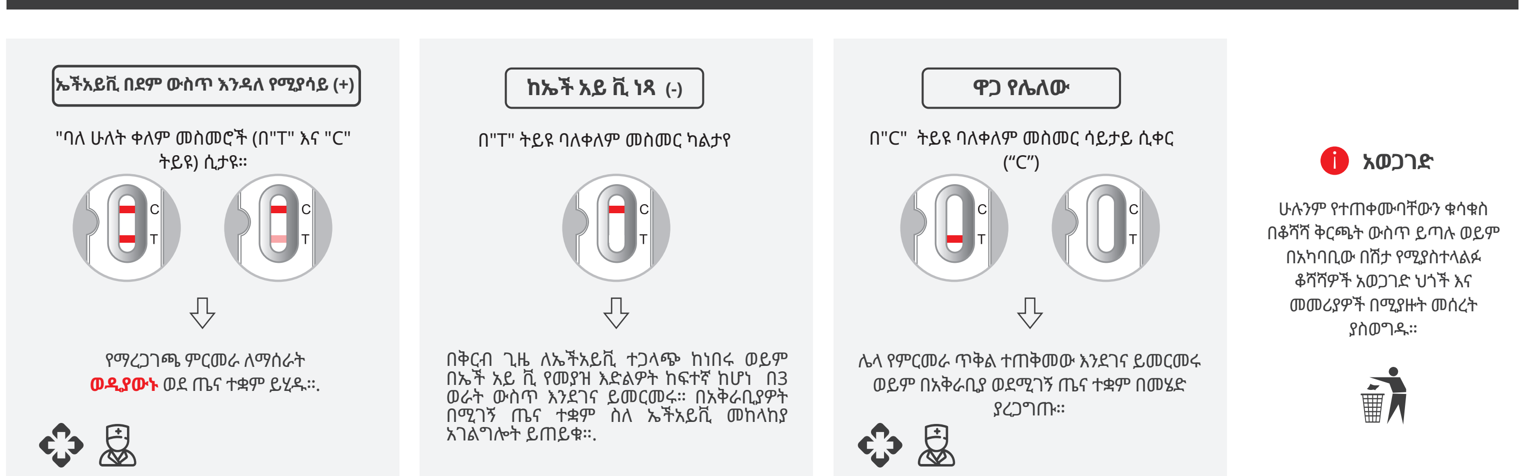
ቅድም ዝግጅት



(ከጣት በሚወሰድ ደም የሚሰራ) የምርመራ ጥቅል አጠቃቀም



ውጤት እንዴት ይነበባል?



ኤች አይ ቪ ምንድን ነው?

1. ኤች አይ ቪ ምንድን ነው?

ኤች አይ ቪ(ቫይረስ) ሰውነታችን በተዋህሲያን ሲጠቃ ምላሽ የሚሰጡ የበሽታ መከላከል ሥርዓት አካል የሆኑ ሲዲ 4 ተብለው የሚጠሩ ህዋሶችን በተለይ ያጠቃል። ቫይረሱ በሲዲ 4 ውስጥ ገብቶ በመራባትና ህዋሱ ላይ ጉዳት በማድረስ ያጠፋቸዋል።በጥምረት የሚሰጡትን ውጤታማ የጸረ ኤች አይ ቪ መድኃኒቶች ካልተወሰደበት፤ የሰውነትን የበሽታ መከላከል አቅም ሙሉ በሙሉ በማዳከም ሰውነታችን በተዋህስያን በቀላሉ እንዲጠቃና በሽታን መቋቋም እንዲሳነው ያደርጋል።

2. ኤችአይቪ እንዴት ይተላለፋል?

የኤች አይቪ ተህዋስ ቫይረሱ በደሙ ውስጥ በአለበት ሰው ደም ውስጥ፣ የወንድ (የዘር ተሸካሚ) ፈሳሽ፣የሴት ብልትና የፊንጢጣ ፈሳሽ ውስጥ እንዲሁም በጡት ወተት ውስጥ ይገኛል። ኤች አይቪ በሚከተሉት ሁኔታዎች ሊተላለፍ ይችላል

- ኤች አይ ቪ ካለበት ሰው ጋር (በብልት ወይም በፊንጢጣ በሚደረግ) ጥንቃቄ በጎደለው የግብረ ሥጋ ግንኙነት እንዲሁም በጣም አልፎ አልፎም በአፍ የሚደረግ ወሲብም አማካኝነት
- ኤች አይ ቪ ያለበት ደም በመውሰድ
- እንደ መርፌና ሲሪንጅ ወይም ሌሎች የመወጊያ ቁሶች፣ ለቀዶ ጥገና የሚያገለግሉ እና ሌሎች ስለታማ ነገሮችን በጋራ መጠቀም
- ኤች አይ ቪ ከአለባት እናት በእርግዝና፣ በወሊድና ጡት በማጥባት ወደ ፅንስ/ልጅ

የጸረ ኤች አይ ቪ መድኃኒትን በአግባቡ እየወሰዱ የቫይረስ መጠናቸው(ብዛት) መለኪያ መሳሪያው ማንበብ ከሚችለው በታች የሆነ ታካሚዎች የማስተላለፍ ዕድላቸው አነስተኛ/የተገታ ነው።

3. ራሴን መመርመር የሚያስፈለገኝ መቼ ነው?

ለኤች አይቪ የተጋለጡ ወይም በኤች አይ ቪ የመያዝ ዕድላቸው ከፍተኛ የሆኑ ሰዎች የኤች አይ ቪ ምርመራ ማድረግ ያስፈልጋቸዋል። በስፋት ጥቅም ላይ የዋሉት የኤች አይ ቪ መመርመሪያዎች የሚለዩት ሰውነታችን ኤች አይ ቪን ለመቆጣጠር በሚያደርገው ጥረት የሚያመነጫቸውን ጸረ ኤች አይቪ ንጥረ ነገሮች(አንቲቦዲዎች)ን ነው። አብዛኛውን ጊዜ ሰዎች እነዚህን ፀረ ኤች አይ ቪ ንጥረ ነገሮች በቫይረሱ በበተያዙ/በተጋለጡ በ28 ቀናት ውስጥ ያመርታሉ። በተጠቀሰው ጊዜ ውስጥ ፀረ ኤች አይ ቪ ንጥረ ነገሮችን በሚለዩ መሳሪያዎች የተመረመረ ሰው በስህተት ነፃ ሊባል ይችላል። ለኤች አይ ቪ ተጋላጭ የሆኑ ሰዎች በተቻለ ፍጥነት መመርመር ቢኖርባቸውም ከ28 ቀን ወዲህ ተጋላጭነት ኖሯቸው በምርመራ ከኤች አይ ቪ ነጻ የተባሉ ሰዎች ከ3 ወር በኋላ በሚደረግ ምርመራ ውጤታቸው መረጋገጥ ይኖርበታል።

4. ውጤቴ ኤች አይ ቪ እንዳለብኝ ቢያመላክት ምን ማድረግ አለብኝ?

ውጤቱን በተጨማሪ ምርመራ ለማረጋገጥ የጤና ባለሙያ ክትትል ማድረግ አለበዎት። ያን ጊዜ የጤና ባለሙያው/ የጤና ተቋሙ ቀጣይ ስለሚኖረው ሂደት ያማክሩዎታል።

የምርት መረጃ

የመዝገብ መለያ(ካታሎግ) ቁጥር

W006P0058 W006P0059 W006P0060

ምርቱ የታለመለት አገልግሎት/ጠቀሜታ

የየወንድፎ የራስ(በራስ) መመርመሪያ ጥቅል ለአንድ ጊዜ ብቻ የሚያገለግል ከጣት በመብጣት በሚወሰድ ደም ኤች አይ ቪ 1/2ን ለመመርመር የሚያገለግል መሳሪያ ነው። በግል ራስን ለመመርመር እና ወይም በባለሙያ ለሚደረግ ምርመራ እንዲያገለግል ታስቦ የቀረበ መመርመሪያ ነው።

ለ'ቪትሮ'/ናሙና ላይ ለሚደረግ ምርመራ ብቻ እንዲያገለግል የተዘጋጀ ነው።..

የአሰራር ቅደም ተከተል መርሆች

ወንድፎ ኤችአይቪ ራስን መመርመሪያ፤ ድርበ አንቲጅንን በማጣበቅ በመመርመሪያው ውስጥ እንዲሰራጩ የማድረግ አሰራርን ይከተላል። ናሙናውና ፈሳሹ በተዘጋጀላቸው ቋት ከተጨምሩ በኋላ በካፒላሪ መርህ መሰረት በመመርመሪያ መሳሪያው ውስጥ ይጓጓዛሉ። የፀረ ኤች አይ ቪ 1/2 ንጥረ ነገር(አንቲቦዲ) በተለያየ መልኩ ከተዘጋጁ ጅፒ 41 ና 36 ከሚባሉ የኤች አይ ቪ አንቲጅኖች ጋር የተለያየ መስተጋብር ይፈጥራሉ። በደም ውስጥ ያሉት የፀረ ኤች አይ ቪ 1/2 አካላት መጠናቸው(ብዛታቸው) መሳሪያው ማንበብ በሚችለው ልክ ወይም ከዚያ በላይ ከሆነ ውጤት ማንበቢያው ቦታ ላይ ባለው መርመሪያ ቦታ("T") ባለቀለም መስመር ይታያል። ይሄም ኤች አይ ቪ በደም ውስጥ መኖሩን ያመለክታል። ምንም አይነት የፀረ ኤች አይ ቪ 1/2 አካላት ከሌሉ ወይም መጠናቸው(ብዛታቸው) ከመሳሪያው የመለየት አቅም በታች ከሆነ ከ"T" ትይዩ ባለው ቦታ ላይ ምንም አይነት መስመር ስለማይኖር ነፃ ውጤትን ያመለክታል። እንደ ውስጣዊ የአሠራር መቆጣጠሪያ ሆኖ እንዲያገለግል በመቆጣጠሪያ ክልል ("C") ትይዩ ባለ ቀለም መስመር ያሰምራል።

አንድ የመመርመሪያ ንጣፍ በተለያየ ሁኔታ የተዘጋጁ የኤች አይ ቪ ና የጥንቸል አንቲጅኖችን ይይዛል። የምርመራ መስመሩ የኤች አይቪ፤የመቆጣጠሪያ መስመሩ ደግሞ የጥንቸል አንቲጅኖችን በተለያየ ቅንብር ያካተቱ ናቸው።

ማስጠንቀቂያና ማሳሰቢያዎች

- የመመርመሪያ ጥቅሉ የአገልግሎት ጊዜው ያለፈበት ከሆነ አይጠቀሙት፡
- እሽጉ ከተበሳ/ከተቀደደ ወይም በአግባቡ ታሽጎ ካልተገኘ አይጠቀሙት
- ከ12 ዓመት በታች የሆኑ ህጻናት በመመርመርያ ጥቅሉ ራሳቸውን መመርመር የለባቸውም።
- ደም (መፍሰስ) በቀላሉ የማይቆምለዎት ከሆነ ራስዎትን መመርመር የለብዎትም።
- ኤች አይ ቪ በደምዎት ውስጥ እንዳለ የሚያውቁ ከሆነ ራስዎትን በራስዎት መመርመር የለበዎትም።
- ምርመራውን ለማከናወን ዝግጁ ካልሆኑ የመመርመሪያውን እሽግ አይክፈቱ
- ምርመራውን ከማከናወንዎት በፊት እጅዎትን ታጥበው ንፁህእና እርጥበት የሌላቸው መሆኑን ያረጋግጡ።
- የምርመራ ውጤቱን ለማንበብ የሚያስችል በቂ ብርሃን አስፈላጊ ነው።.

የጥቅሉ ይዘት

የምርመራ ጥቅሉ በ3 መንገድ ታሽጎ ይቀርባል። አንድ እሽግ ውስጥ 1፣ 20 ወይም 100 የመርመሪያ እሽጎችን ሊይዝ ይችላል።

በጥቅሉ ውስጥ የተካተቱ ቁሶች ዝርዝር በሚከተለው ሰንጠረዡ ተዘርዝረዋል።

ቁሳቁስ ዝርዝር	የመለያ ቁጥር	W006P0058	W006P0059	W006P0060
የመመርመሪያ ጥቅሉ	የመመርመሪያ መሳሪያ (በቁጥር)	1	1x20	1x100
	የብልሽት መከላከያ (በቁጥር)	1	1x20	1x100
ተጨማሪ ቁሶች	ናሙና መውሰጃ (በቁጥር)	1	1x20	1x100
	በፈር/ፈሳሽ በቢልቃጥ)	1	1x20	1x100
	የአጠቃቀም መመሪያ(በቁጥር)	1	1x20	1x100
	ለአንድ ጊዜ የሚያገለግል የጣት መውጊያ (በቁጥር)	1	1x20	1x100
	በአልኮል የተነከረ ማፅጃ እሽግ (በቁጥር)	1	1x20	1x100
	ባለዘንግ የጥጥ ማድረቂያ (በቁጥር)	1	1x20	1x100
	የቆሻሻ ማስወገጃ ላስቲክ (በቁጥር)	1	/	/

ደህንነቱን ጠብቆ ማከማቸት (ማስቀመጥ)

1. የምርመራ ጥቅሉ ከ2-30 ዲግሪ ሴንቲ ግሬድ ውስጥ ለ 24 ወራት ሊከማች ይችላል.
2. የመመርመሪያ መሳሪያው እሽግ በተከፈተ ከ 1 ሰዓት ባልበለጠ ጊዜ ውስጥ ይጠቀሙበት
3. የፀሀይ ብርሀን, እርጥበት እና ሙቀት በማያገኙት ቦታ ያስቀምጡት
4. (ምርመራ ለማከናወን) የመመርመሪያ ጥቅሉን ከ10-30 ዲግሪ ሴንቲ ግሬድ በሚደርስ ሙቀት መጠን ይጠቀሙ።

የምርመራ ሂደቱ ውስንነቶች

1. መሳሪያው የታቀደው ከሰው ጣት የሚወሰድ ደምን ለመመርመር ነው።
2. ምርመራው ለኤችአይቪ-1 እና 2 የሚዘጋጁ ፀረ እንግዳ አካላትን መኖራቸውን እንጅ መጠናቸውን አያሳይም።
3. ምርመራው በሚከናወንበት ጊዜ የአሰራር ሂደቱን እና የውጤት ንባብና ትርጉም ጥብቅ ክትትል ይፈልጋል። ለተሻለ የምርመራ አፈጻጸም፣ ትክክለኛ የናሙና አአወሳሰድ ወሳኝ ነው። የአሰራር ሂደቱን አለመከተል የተዛባ (የተሳሳተ) የምርመራ ውጤት ሊሰጥ ይችላል።
4. በስህተት ከኤች አይ ቪ ነፃ የሚል ውጤት የሚከሰትባቸው ሁኔታዎች
   - ከ 3 ወር ወዲህ ለኤችአይቪ የተጋለጡ ተመርማሪዎች
   - የፀረ-ኤችአይቪ መድኃኒት እየወሰዱ ላሉ ታካሚዎች
   - በናሙናው ውስጥ የሚገኙት የኤችአይቪ ፀረ እንግዳ አካላት(አንቲቦዲ) መጠን(ብዛት) ከመመርመሪያው የማንበብ አቅም በታች በሚሆንበት ጊዜ
5. በስህተት ኤች አይ ቪ በደም ውስጥ አለ የሚል ውጤት የሚከሰትባቸው ሁኔታዎች
   - በኤችአይቪ ክትባት ሙከራ ውስጥ የሚሳተፉ ግለሰቦች
6. "C" ላይ መስመር መኖሩ የተጨመረው ፈሳሽ እስከምልክቱ ድረስ መሰራጨቱን ከመጠቆም ባለፈ
   - ትክክለኛው ናሙና ስለመጠቀምም ሆነ
   - ናሙናው በተገቢው መንገድ ስለመጨመሩ አያመለክትም።
7. ልክ እንደ ሁሉም መመርመሪያዎች የመጨረሻው ትክክለኛ የምርመራና ሕምክና ውሳኔ በዚህ አንድ ነጠላ ምርመራ ውጤት ላይ የተመሰረተ መሆን የለበትም። ይልቁንም በጤና ባለሙያዎች በሚደረግ መጠይቅና የአካላዊ ምርመራ እንዲሁም ከሌሎች ተጨማሪ የላቦራቶሪ ምርመራ ውጤት ግኝቶች ጋር ተገናዝቦ የሚወሰን ይሆናል። የወንድፎ የኤችአይቪ ራስን(በራስ) መመርመሪያ ውጤትን እንደ ብቸኛ የውጤት መወሰኛ መጠቀም አይገባም።

የአፈጻጸም ባህርያት

የመመርመሪያውን ውጤታማነት ለማጥናት የኤችአይቪ ውጤታቸው የማያውቁ 900 ተሳታፊዎች ራሳቸውን እንዲመረመሩ የወንድፎ የኤችአይቪ ራስን(በራስ) መመርመሪያ ጥቅል ተሰጣቸው። ውጤታቸው ከ 4 ኛ ትውልድ በቤት ሙከራ ከተከናወነ ምርመራ ውጤት ጋር ተነፃፀረ። የቤተሙከራው ምርመራም 77 ተሳታፊዎች ኤችአይቪ እንዳለባቸው፤ 822 ተሳታፊዎች ደግሞ ከኤችአይቪ ነጻ እንደሆኑ ሲያሳይ የ1 ተሳታፊ ውጤት ዋጋ አጥቷል። በድምሩ 43 ተሳታፊዎች (5 ኤችአይቪ ያለባቸው፣ 37 ኤችአይቪ የሌለባቸው እና 1 ዋጋ የሌለው ውጤት) ከአፈጻጸም ትንተና ውጭ ሆነዋል። የውጤቶቹ ንጽጽር እንደሚከተለው ነበር፦

- 95.8% ተሳታፊዎች (69/72) ውጤት በትክክል ኤች አይ ቪ እንዳለባቸው ሪፖርት ተደርጓል። ይህ ማለት በኤች አይ ቪ የተያዙ 3 ተሳታፊዎች ከኤች አይ ቪ ነፃ ናቸው ተብለዋል ማለት ነው። እንዲህ አይነቱ ክስተት በስህተት ከበሽታ ነፃ መባል(ፎልስ ነጌቲቭ) ተብሎ ይታወቃል።
- 99.6% ተሳታፊዎች (782/785) በትክክል ኤች አይ ቪ እንደሌለባቸው ሪፖርት ተደርጓል። ይህ ማለት በኤችአይቪ ያልተያዙ 3 ሰዎች በስህተት ኤች አይ ቪ እንዳለባቸው ተቆጥረዋል ማለት ነው። ይኽም በስህተት በሽታ አለብህ/ሽ መባል(ፎልስ ፖዘቲቭ) ተብሎ ይጠራል።
- ከተሳታፊዎቹ ውስጥ 4.7% (42/900)ን ውጤት ማግኘት አልተቻለም። የ 1 ተሳታፊ የኤችአይቪ ውጤቱ በጥናቱ ወቅት ባለመረጋገጡ ከትንተናው እንዳይካተቱ ተደርጓል!

ዋቢዎች(ማጣቀሻዎች)

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.

የምልክቶች መፍቻ

IVD	ናሙና ላይ የሚደረግ ምርመራ		የአጠቃቀም መመሪያውን ይከተሉ		የአገልግሎት ዘመን ማብቂያ ጊዜ እኤአ
Σ	ለምርመራው በቂ ቁጥር አካቷል		የተመረተበት ቀን። እኤአ		በደረቅ ቦታ ይቀመጥ
LOT	የባች ኮድ (የምርት ክምችት ምልክት)		የሙቀት መጠን ገደብ		የፀሐይ ብርሃን በማያገኘው ቦታ ይቀመጥ
	አምራች		በድጋሚ የማያገለግልS	REF	የምርት መለያ/ የካታሎግ(የመዝገብ
	የጥንቃቄ መልዕክት		እንዴት በአንድ ልብ ውስጥ አልቻልኩም ለመከላከል ወቅታዊ መረጃ ይምረጡ።		

የአምራቹ መረጃ

ጓንግዡ ወንድፎ ባዮቴክ ኃላፊነቱ የተወሰነ ኮ

አድራሻ ቁ 8 ሊዢሻን ጎዳና ሳይንስ ከተማ ሎጋንጅ ወረዳ 510663 ጓንግዡ የሕዝባዊ ሪፐብሊክ ቻይና፡ ቻይና
ስልክ +86-20-32296083 400-888-5268 (ነፃ የጥሪ ማዕከል)
ፋክስ +86-20-32296063
ኢሜይል global@wondfo.com.cn
ገፀ ድር en.wondfo.com

ከምርቱ ጋር በተያያዘ ማንኛውም ጥያቄ ካለውት አምራቹን ወይም በአቅራቢያዎት የሚገኝ አከፋፋይን ማግኘት ይችላሉ።

ENGLISH

Rev. A7 Rel.: 2023/03/31

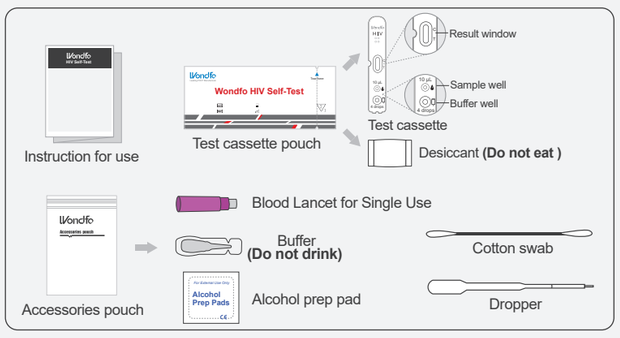
Wondfo HIV Self-Test

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

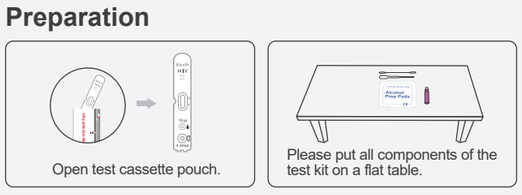
Contents



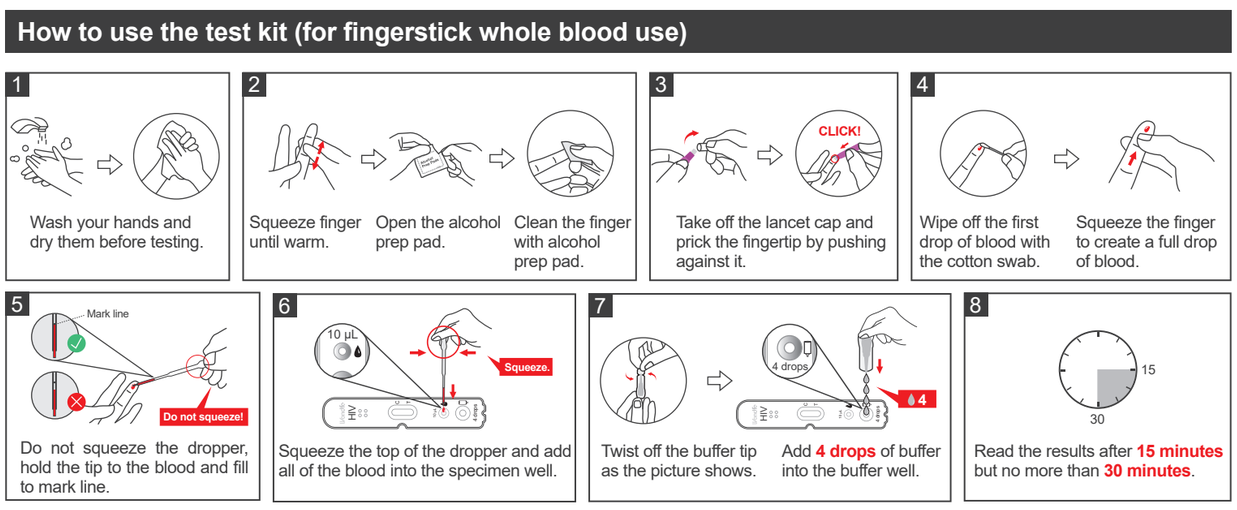
Materials may be required but not provided.

Timer Tissue Bandage

Preparation



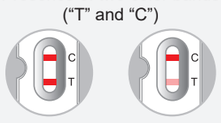
How to use the test kit (for fingerstick whole blood use)



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.

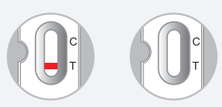
Negative (-)

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

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	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.

Add: No.8 Lizhishan Road, Science City, Huangpu 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: en.wondfo.com

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

LUO

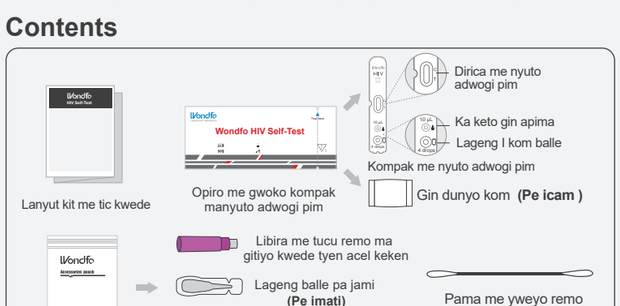
Wondfo HIV Self-Test

Nyuto kit me tic kwede

- Myero I lub kit me pim maber twatwal kit ma onyutte wek inong adwogi ma atir dok I wange
- Bed I kabedo maleng, matye ki deer ki nen ni itye ki jami me pim weng mapud pe icako pim.
- Me tic kwede tyen acel keken. Pe iyab opiro matye ki jami pim ka pud pe itye atera me pimme.

Nen vidiyo ma onyuto kit me tic kwede

Contents

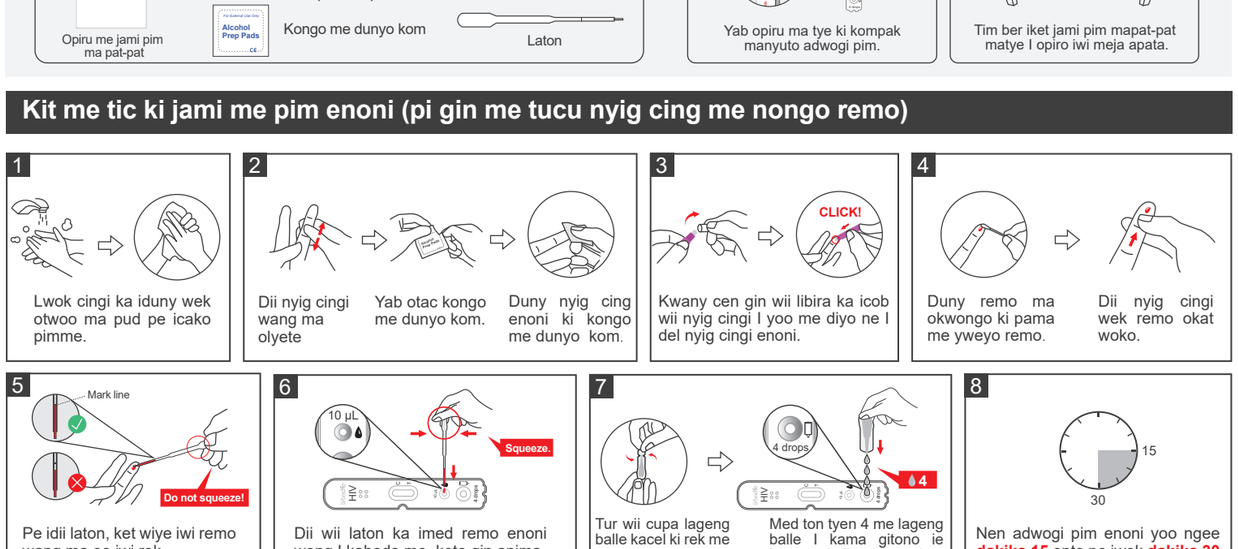


Jami matwero mitte ma pe giketo I ie.

Cawa Lagee kom Bandej

Yubbe

Kit me tic ki jami me pim enoni (pi gin me tucu nyig cing me nongo remo)



Kite me kwano adwogi pim

Tye (+)

Tye pa rek aryo me rangi ma kwar ("T" ki "C")

Wot I ot yat pi pim me moko adwogi man cut cut.

Peke (-)

Kace rek me rangi ma kwar peke ("T")

Pime odoco I ngee dwe 3 kace pe ibedo agwoka I kom kwidi two jonyo I kare ma okato cocoki onyo itye ma kwidi twero maki oyot oyot. Peny kony I kom kit me gengo kwidi two jonyo ki I ot yat macok kwedi.

Peatir

Peke pa rek me rangi ma kwar kama gicoyo ni ("C")

Pim doki onyo wot I ot yat me moko adwogi pim enoni.

BOL

Bol jami ducu matye I ie I gin coko yugi onyo baa kit ma lubbe ki cik me kabedo meno makwako kom bayo yugi makeme ki two/kwidi matwero kobo.

Peny ki Lagam

1. Kwidi two jonyo (HIV) obedo ngo?

Kwidi two jonyo keme me lweny ki dul kom ma lwenyo I kom kwidi ma kelo two, ma kilwongo ni CD4 cells, ma konyo kom me lweny I kom kwidi ma odonyo I kom. I kin CD4 cell egoni, kwidi two jonyo nyaa ma I yoo ngeye cako balo ki nyoto dul kom malwenyo I kom kwidi ma donyo I kom. Labongo kony me yat mapat-pat magirubo kacel me lweny I kom kwidi two jonyo (ARV), dul kom ma lwenyo I kom kwidi madonyo I kom bidoko goro ma dong pe romo ka lweny I kom kwidi ki two mukene mapat-pat.

2. Kwidi two jonyo kobo nining?

Kwidi two jonyo nonge I pig kom mapat-pat pa dano matye kwo ki kwidi enoni, ma I kin pig kom egonoi obedo remo, lac nyodo, pig ter mon, pi ma aa ki I ngwiny cet ki cak kor. Kwidi two jonyo twero kobo I yoo me:

- Butu kun nongo lacoo odonyo I ter dako onyo I ngwiny cet, ki, ma dong pe maro time twatwal, tic ki dog I kare me buto ki ngat matye ki kwidi two jonyo.
- Medo remo ma oballe/tye ki kwidi two jonyo I kom dano mo.
- Poko libira, ki jami mukene me cobo dano, yango dano onyo gino mo keken ma bit.
- Aa ki I kom mego matye ki kwidi two jonyo me kobo I kom latin I kare me yaco, nywal onyo dot.

Kace ngat matye ki kwidi two jonyo tye kamwonyo yat me lweny I kom kwidi two jonyo (ARV) ma kweyo teko pa kwidi enoni, gum mege me kobo kwidi enoni I kom ngat mukene jwik mada.

3. Awene ma mitte ni myero apimme?

Dano ma obedo onyo otimo gin mo cocoki ma weko kwidi two jonyo twero mako gi onyo pi tic onyo gin ma gitimo weko bedo yot tutwal ki kwidi two jonyo me kobo I kom gi myero opimme. Yoo mapat-pat me pimo pig kom ma lwenyo I kom kwidi two jonyo ma oywek twatwal I lobo nongo pig kom manonge I remo ma kom dano enoni okati kwede me lweny I kom kwidi two jonyo. I kare mapol, kom kati ki pig kom me lweny I kom kwidi two jonyo manongo pud nino 28 pe okato I ngee nongo kwidi two jonyo. I kare man, adwogi pim twero nyuto ni kwidi two jonyo peke kace gibutiyo ki pig kom ma nonge I remo ma lwenyo I kom kwidi two jonyo me ngeyo kace mako pig kom ma lwenyo I kom kwidi two jonyo tye. Kadi bed ni dano ma kwidi two jonyo twero mako gi oyot-oyot myero opimme cut kace twere, nongo ni kwidi peke I komgi ma pud nino 28 pe okato myero gilub ki pim mukene yoo ngee dwe adek.

4. Ngo ma myero atim kace anongo ni kwidi two jonyo tye?

Myero inen daktar me pimo ne odoco wek imok adwogi pim enoni. I kare enoni ot yat macok kwedi kacel ki daktar enoni bimini tam I kom ngo ma dongo omyero itim I kare enoni. At that time your local clinic and the provider will suggest the next steps that need to be taken.

Ngec ma kwako kom gin pim man

NAMA MA GIMIYO PIRE

W006P0058 W006P0059 W006P0060

TIC MA GIKETO PIRE

Gin pimo kwidi ma gilwongo ni obedo Wondfo HIV Self-Test obedo gin pimo kwidi two jonyo kekeni ki I remo magikwanyo ki iwi nying cing pi kwidi two jonyo (HIV -1/2). Giyubo me pime kekeni ki/onyo daktari bene.

Pi pimo kwidi ki I remo keken.

YOO ME ALUBA I KARE ME PIMO KWIDI

Wondfo HIV Self-Test tiyo ki yoo me pim kwidi ma kun nongo giketo gin ma gibupimo enoni I kom karatac ma giliro mabor. Kadong giketo remo me apima ki gin me gwoko balle I kabedo gi mapat-pat, gibiwot I gin me pim enoni I yoo me motto I paipo matye. Pig kom manonge I remo ma kom dano enoni okati kwede me lweny I kom kwidi two jonyo (HIV-1 and/or HIV-2 antibodies) moko I kom kwidi two jonyo ka make kacel I yat moni ma pii-pii me rangi jabu (gp36/41), kadong kwidi ki jami ma orubbe kacel enoni (gp41 and gp36) weng coke I kabedo ma gicoyo ie ni (T). Kace dwong pa pig kom manonge I remo ma kom dano enoni okati kwede me lweny I kom kwidi two jonyo kwidi two jonyo (HIV-1 or HIV-2) tye rom onyo kato wii rwom madong twero nen (limit of detection (LOD) I kare me pim, obinyuto rek kama gicoyo ie ni (T) ki dong man nyuto ni kwidi two jonyo tye. Kace dwong pa pig kom manonge I remo ma kom dano enoni okati kwede me lweny I kom kwidi two jonyo kwidi two jonyo (HIV-1 or HIV-2) peke onyo pe kato wii rwom madong twero nen (limit of detection (LOD), rek I kabedo ma gicoyo I ie ni (T) bibedo peke, ma nyuto ni kwidi two jonyo peke. Me tic macalo lanyut ni gin pim man tye katic maber I kare me pim, rek moni bibedo tye I kabeo ma gicoyo ie ni (C).

CIMO WANG KI JUK

Pe itii ki gin pim enoni kace nino ne dong okato.
Pe itii kede kace opiru otuc onyo pe gimwono maber.
Pe ipimme kekeni kace pud mwaka ni pe oo 12.
Pe ipimme kekeni kaceitye ki peko me cwer pa remo.
Pe ipimme kekeni kace dong gipimi dok ginongo ni itye ki kwidi two jonyo
Pe iyab opiru wang ma dong itye atera me cako pimme.
Lwok cingi dok nen ni cingi tye maleng dok ma otwoo maber mapud pe ya icako pimme. Deero ma oromo mitte wek inen adwogi pim enoni.

NGO MATYE I IYI OPIRU ENONI

Watye ki dul me gin pim egoni adek mapat-pat, 1 pim/gin pim, 20 pim/jami pim ki 100 pim/jami pim. Jami pim mapat-pat onyutte kit ma tye piny kany:

Components \ Catalog No.		W006P0058	W006P0059	W006P0060
Opiru kompak me nyuto adwogi pim	Kompak me pim (pcs)	1	1x20	1x100
	Gin dunyo kom (pcs)	1	1x20	1x100
Ngo matye I iye	Laton (pcs)	1	1x20	1x100
	Gin me gengo balle (vial)	1	1x20	1x100
	IFU (pcs)	1	1x20	1x100
	Libira me tuco remo ma gitiyo kede tyen acel (pcs)	1	1x20	1x100
	Kongo me dunyo kom	1	1x20	1x100
	Pama me yweyo remo	1	1x20	1x100
	Disposal bag (pcs)	1	/	/

Karatac acel magiliro mabor tye ki: Jami mapol ma girubo kacel ma okelo rangi jabu (HIV gp41/gp36 ma giribo ie pig kom ma lwenyo I kom kwidi two jonyo ka makke kacel I yat moni ma pii-pii me rangi jabu ki pig kom ma lwenyo I kom kwidi two jonyo ma ooa ki I wat kom apwoyo ma omoko I kom yat moni ma pii me rangi jabu), Rek ma nyuto pim (HIV gp41 ma giribo ie kwidi two jonyo ki HIV gp36 ma giribo ie kwidi two jonyo) ki dong rek ma onyuto ni gin pim man tye katic maber (pig kom ma lwenyo I kom kwidi two jonyo ma o oak I kom dyel ki apwoyo IgG).

GWOKO KI KETO NE MABER

1. Gitwero gwoko jammi me pim egoni I lyeto piny matye I kin 2-30°C pi dwe 24.
2. Tii ki kompak me pim enoni mapud cawa acel pud pe okato I ngee yabo opiru.
3. Gwok ki ceng, ngico ki lyeto.
4. Tii ki gin pim enoni I lyeto piny matye I kin 10-30 °C

PEKI MATYE KI YOO ME PIMO REMO MAN

1. Gi yubo pim man I yoo ma myero gipim remo weng ma ginongo I ngee tucu nyig cing ki libira.
2. Pim man gik ki neno ka pig kom malwenyo I kom kwidi two jonyo HIV-1 ki HIV-2 tye onyo peke.
3. Myero gilub yoo me pim ki ngiyo iyi adwogi maber madaa kace gitye kapimo pim enoni. Me weko pim man owot maber, pire tek tutwal ni gikwanyo remo me apima I yoo maber dok kit ma mitte. Bwoc lubo yoo me pim kit ma mitte twero weko adwogi ma kakare pe nonge.
4. Adwogi ma nyuto ni kwidi two jonyo peke kun nongo pe kakare twero timme pi tyen lok magi:
   - Kace dwe 3 pud pe okato ma ngat enoni otimo gin ma weko kwidi two jonyo twero make.
   - Lutwoo matye ka nongo yat me lweny I kom kwidi two jonyo (ARV).
   - Kace rwom me pig kom ma lwenyo I kom pig kom ma lwenyo I kom kwidi two jonyo matye I gin pim enoni tye piny ma pe oo I wom mamitte me pim enoni.
5. Adwogi ma nyuto ni kwidi two jonyo tye kun nongo pe kakare twero timme pi tyen lok magi:
   - Kace ngat enoni obedo I yub mo me temo yat me lweny I kom kwidi two jonyo.
6. Tye pa rek ma nyuto ni gin pim man tye katic maber nyuto ni wot pa gin ma pii-pii ma gimedo otimme. Man pe nyutto cikke ni:
   - Gitiyo ki gin apima ma atir.
   - Giketo gin apima I yoo ma atir.
7. Kit ma timme I pimo kwidi ducu, moko tye onyo peke pa kwidi myero pe obed I ngee pim tyen acel keken ento myero daktar aye omok tye onyo peke pa kwidi ma lubbe ki neno adwogi pim ma oa ki I labaratori ki neno/ngiyo iyi adwogi enoni maber. Myero pe gitii ki adwogi ma ginongo I ngee pimo kwidi two jonyo ki Wondfo HIV Self-Test keken me moko ne.

KIT MA GIN PIMO KWIDI ENONI TIYO KWEDE

I kwed ma gitimo, gimiyo Wondfo HIV Self-Test ki dano 900 ma bedo tye/peke pa kwidi two jonyo I komgi pe ongene wek gupimme. Giporo adwogi egoni ki adwogi maginongo ki I ot pim (labaratori) matye ki rwom, ngec ki diro manyen. Aadwogi ma oak i I ot pim (labaratori) onyuto ni well dano ma room 77 obedo ki kwidi two jonyo, 822 obedo peke ki kwidi two jonyo ki dong 1 obedo ma adwogi pim mege niang ie obedo tek. Giweko dano 43 (5 ma obedo tye ki kwidi two jonyo, 37 obedo peke ki kwidi two jonyo ki 1 obedo ma adwogi pim mege niang ie obedo tek) cen ki I tic me ngiyo ki lwodo iwi kit ma gin mi pimo kwidi two jonyo enoni otimo kwede. Poro adwogi pim ma otimme obedo kit ma onyute piny kany:

- 95.8% pa jo ma opimme (69/72) odwoko ni adwogi pimgi onyuto ni kwidi tye. Man tere ni dano 3 ma obedo ki kwidi two jonyo onyuto ni gi peke kwede. Man gilwongo ni adwogi ma nyuto ni kwidi two jonyo tye kun nongo man pe kakare.
- 99.6% pa jo ma opimme (782/785) odwoko adwogi pim ma onyuto ni gipeke ki kwidi ma obedo adwogi ma kakare. Man tere ni dano 3 ma obedo peke ki kwidi onongo adwogi ma onyuto ni gitye ki kwidi. Man gilwongo ni adwogi ma onyuto ni kwidi two jonyo tye kun nongo man pe kakare.
- 4.7% pa jo ma opimme (42/900) obwoc nongo adwogi, pe gimoko adwogi me pimo kwidi two jonyo pa ngat acel I kin jo ma opimme I kare me kwed ma oweko giweke I kare me ngiyoki lwodo iwi adwogi.

KAMA NGEC MAN ONONGE KI IE

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 — *Gin pimo kwidi ki I kom*	Lanyut I kom kit me tic kwede	Nino ne me balle
Twero pimo manok onyo makato	Nino ma kiyubo iye	Gwok obed ma otwoo
LOT — Nama ma kimiyo ki jami ma giyubo I nino enoni	Lyeto/ngico ma oporre	Gwok ki ceng
Jo ma oyubo	Pe itii kede odoco	REF — Nama ma gimiyo ki gin pim man
Juk	Pe itii kede Yore/Jami ame onyutte ka pe tye atic onyo ka obale oko, dang dok pore me nwongo tam ame rwatte kede yore me tic kakare	

TYEN LOK PA ALAMA MAPAT-PAT

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Site web: en.wondfo.com

Tim ber Ilok ki jo ma oyubo onyo lacat me kabedo megi kace itye ki lapeny ma lukke ki gin pimo kwidi two jonyo man.

LUGANDA

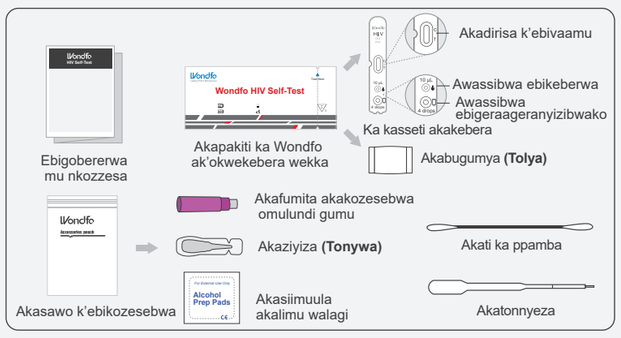
Wondfo HIV Self-Test

Nyuto kit me tic kwede

- Oteekwa okugoberera emitendera gy' okukebera n' obwegendereza okufuna ebivaamu ebituufu.
- Tuula mu kifo ekiyonjo, ekitangaala obulungi era okakase nti olina byonna bye weetaaga nga tonnatandika kukebera.
- Bya kukozesa mulundi gumu gwokka. Tosumulula kasawo omuli ka kkaseti okutuusa nga weetegese okukebera.

Laba viidiyo y' enkozesa

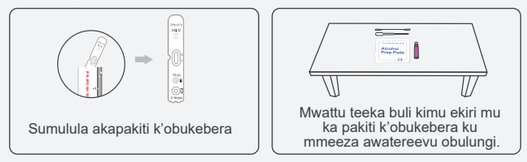
Contents



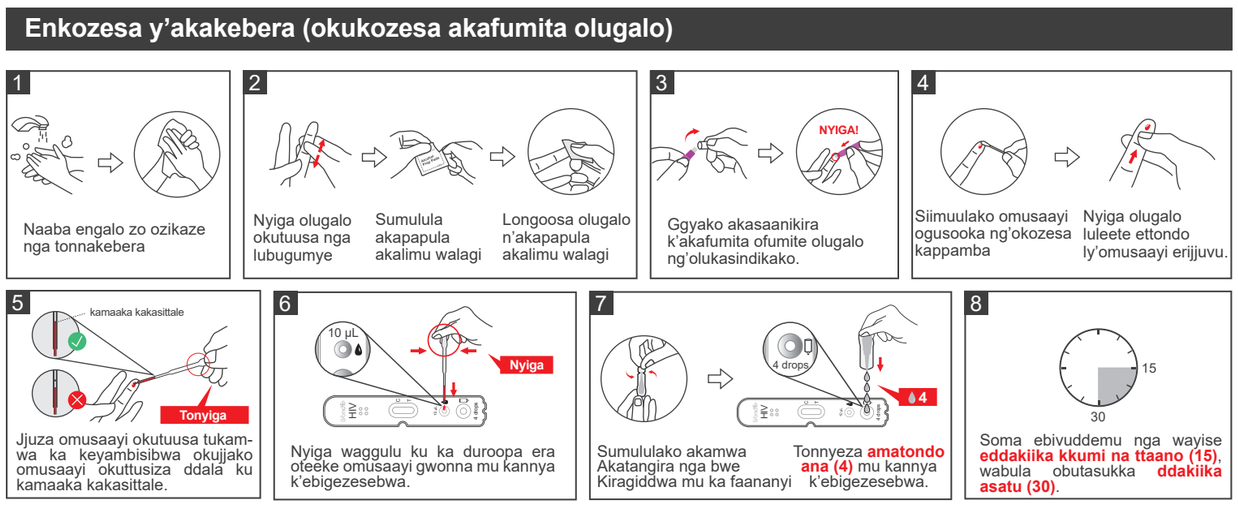
Ebikozesebwa ebisobola okwetaagisibwa naye nga tebikuwereddwa

Essaawa | Akasiimuula | Bandegi

Okutegeka



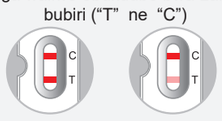
Enkozesa y'akakebera (okukozesa akafumita olugalo)



Engeri y'okusoma ebivuddemu

Omulwadde (+)

Nga waliwo obukuubo bwa Langi bubiri ("T" ne "C")



Genda mu ddwaliro ofune okukeberwa okukakasa amangu ddala nga bwe kisoboka.

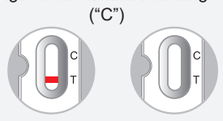
Omulamu(-)

Nga tewali kakuubo ka Langi ("T")

Ddamu weekebere mu myezi esatu (3) bw'oba nga wayitako mumbeera eyiza okukuletera akawuka HIV emabegako oba bw'oba ng'oli mu bulabe bwa maanyi obw'okumufuna. Buuza ebikwata ku kwewala HIV mu ddwaliro erikuli okumpi.

Kafu

Nga tewali kakuubo ka langi ("C")



Kola okukebera okulala oba genda mu ddwaliro bakukebere okukakasa.

OKUSUULA

Suula ebintu byonna mu kasasiro owa bulijjo oba bisuule ng' ogoberera amateeka n' ebiragiro by' eggwanga ku kasasiro ow' engeri eno.

Ebibuuzo n'okwanukula

1. Akawuka ka siriimu (HIV) kye ki?

Akawuka ka siriimu (HIV) kalumba obutaffaali,bw' abaserikale obuyitibwa obutaffaali bwa CD4, nga bwe buyamba omubiri okulwanyisa endwadde. Mu kataffaali ka CD4, HIV yeekubisaamu era ekivaamu, akosa era nanafuya obutaffaali. Bwe watabaawo kujjanjabwa bulungi n' eddagala lya ARV, omuyungo gw' obusibage gunafuyizibwa ne gutuuka nga tegukyasobola kulwanyisa buwuka oba ndwadde.

2. HIV atambuzibwa atya?

HIV asangibwa mu gamu ku mazzi g' omu mubiri ag' abantu abalina HIV, omuli omusaayi, enkwaso, amazzi g' omu bukyala, amazzi g' emabega n' amabeere. HIV asobola okutambulira mu:

- Okwegatta kw' omu bukyala n' emabega okutaliimu kuziyiza, ne mu biseera ebitono ennyo, mu kwegatta kw' omu kamwa n' omuntu alina HIV.
- Okussibwako omusaayi ogulimu akawuka.
- Okugabana empiso, ebibomba, ebifumita ebirala, ebikozesebwa ebirala mu kulongoosa oba ebintu ebirala eby' obwogi.
- Okuva ku maama alina HIV okudda ku mwana we mu kiseera ng' ali lubuto, ng' azaala oba ng' ayonsa

Omuntu alina HIV bw' abeera ku ART (eddagala eriweweeza ku kawuka), nga likendeeza bulungi HIV mu mubiri, omukisa gwe okusiiga omuntu omulala HIV gukendeera nnyo.

3. Ddi lwe neetaaga okwekebera?

Abantu ababaddeko mu mbeera erimu HIV oba abali mu bulabe bw' okufuna HIV balina okwekebeza. Okukebera HIV okusinga okukolebwa kulaba antibody obuziyiza omuntu ng' obusibage bwe bugezaako okulwanyisa HIV. Ebiseera ebisinga, abantu bafuna obuwuka bwa ssiriimu [bu antibodies] mu nnaku 28 oluvannyuma lw' okufuna akawuka. Mu kiseera kino, ebiva mu kukebera biyinza okulaga nti omuntu talina kawuka bw' aba akebeddwa antibody. Newankubadde abantu abali mu bulabe bw' okufuna HIV balina okwekebeza amangu ddala ng abwe kisoboka, okukebera okulaba nti omuntu talina kawuka mu nnaku 28 okuva lwe yali mu mbeera eyo kulina okukakasibwa ng' addamu okukeberwa mu bbanga eritasukka myezi esatu oluvannyuma.

4. Kiki kye nnina okukola nga nzuuliddwa nti nnina akawuka?

Olina okukirondoola n' omusawo okulaba ng' oddamu okukeberwa okukakasa ebyo by' ofunye. Mu kiseera ekyo, eddwaliro ly' omu kitundu kyo n' abakusasulira bajja kukubuulira emitendera egyetaagisibwa okuyitibwamu.

Ebikwata ku kakebera

ENNAMBA Y' AKAKEBERA

W006P0058 W006P0059 W006P0060

KYE KALINA OKUKOZESEBWA

Akakebera ka HIV aka Wondfo kuuma akakozesebwa okwekebera nga kakozesa akafumita engalo okukebera HIV-1/2. Kagendererwamu okukozesebwa mu kwekebera ne/oba okukozesebwa abakugu mu byekisawo.

Ka kukeberera mu kacupa mwokka.

EMITENDERA

Akakebera ka HIV aka Wondfo kakozesa enkola ya antigen sandwich immunochromatography ey' emirundi ebiri. Omusaayi ogukeberwa n' ogwo ogw' okugeraageranyizaako bwe gussibwa mu bifo byagwo, gujja kutambulira mu kakebera nga gusikibwa amaanyi g' obutonde. Obuwuka bwa ssiriimu [bu Antibodies] obw' ekika kya HIV-1 ne/oba HIV-2 zeekwata ku antigen za colloidal gold-HIV (gp36/41), era ekivaamu ne kikwatibwa antigen za HIV eza recombinant (gp41 ne gp36) ne zibeera mu kitundu (T) nga tezitambula. Omuwendo gwa antibody za HIV-1 oba HIV-2 bwe guba nga gutuuse oba nga gususse ku ogwo ogutakyasobola kulabwa mu kukebera kuno, kireetawo akakuubo ka Langi akalabika mu kitundu ekikebererwamu (T) era ne kiraga nti omuntu alina akawuka. Omuwendo gwa antibody za HIV-1 oba HIV-2 bwe gubeera zero oba wansi w' omuwendo ogusobola okulabwa, tewaba kakuubo ka Langi kasobola kulabwa mu kitundu ekikebererwamu (T) ekiraga nti omuntu talina kawuka. Okusobola okukola ng' ekyokugeraageranyizibwako, akakuubo aka langi kajja kulabika mu kitundu ekigeraageranyizibwako (C).

OKULABULA N' OKWEGENDEREZA

Tokozesa kakebera bwe kaba nga kaayitako ekiseera.
Tokozesa ng' akasawo kayulise oba nga kaasibwa bubi.
Tokakozesa kwekebera bw' oba nga toweza myaka 12.
Tokakozesa kwekebera bw' oba ng' olina obuzibu mu kuvaamu omusaayi.
Tokakozesa kwekebera bw' oba nga wakeberwa n' osangibwa ne HIV.
Tosumulula kasawo okutuusa nga weetegese okwekebera.
Naaba engalo zo era okakase nti nnyonjo era nkalu nga tonnatandika kwekebera.
Ekitangaala ekimala kyetaagisa okusoma ebivudde mu kukebera.

EBIGENDERA KU KAKEBERA

Waliwo ebika by' obukebera bya mirundi 3, ak' omulundi 1/kakebera, ak' emirundi 20/kakebera n' ak' emirundi 100/kakebera. Ebigendera ku kakebera biragiddwa wammanga:

Ebibaamu \ Ennamba y' Akakebera		W006P0058	W006P0059	W006P0060
Akasawo ka ka kkaseti akakebera	TKa kkaseti akakebera	1	1x20	1x100
	Akabugumya	1	1x20	1x100
Ebigenderako	Akatonnyeza	1	1x20	1x100
	Akageraageranyizibwako	1	1x20	1x100
	IFU	1	1x20	1x100
	Akafumita okufuna omusaayi Kakozesebwa omulundi gumu	1	1x20	1x100
	Akasiimuula akalimu walagi	1	1x20	1x100
	Ka ppamba	1	1x20	1x100
	Akasawo ka kasasiro	1	/	/

Akakebera kamu kabeera: Gold conjugate (HIV gp41/gp36 fusion recombinant antigen-gold colloid and rabbit IgG polyclonal antibody-gold colloid), Test line (HIV gp41 recombinant antigen ne HIV gp36 recombinant antigen) ne Control line (Goat anti rabbit IgG polyclonal antibody).

ENTEREKA N' OBUTEBENKEVU

1. Akakebera kasobola okuterekebwa mu bbugumu lya 2-30 °C okumala emyezi 24.
2. Kozesa ka kkaseti akakebera mu ssaawa 1 okuva lw' osumulula akasawo.
3. Kateeke wala okuva kumusana, amazzi n' ebbugumu.
4. Kozesa akakebera mu bbugumu lya 10-30 °C.

OBUZIBU MU NKOZESA

1. Okukebera kuno kwakolebwa okukebera omusaayi oguggyibwa ku lugalo.
2. Okukebera kuno kuzuula antibody za HIV-1 ne HIV-2.
3. Enkola y' okukebera n' entaputa y' ebivaamu birina okugoberera obulungi mu kukebera. Okusobola okukebera obulungi, okufuna ebikeberwa mu ngeri ennungi kikulu. Okulemwa okugoberera enkola entuufu kiyinza okuviirako okufuna ebivaamu ebikyamu.
4. Okulaga nti tolina kawuka so nga kikyamu kiyinza okubaawo mu mbeera zino:
   - Abalwadde bafunye akawuka mu myezi egitawera 3.
   - Abalwadde bajjanjabwa HIV (Bali ku ARV).
   - Omuwendo gwa antibody za HIV eziri mu musaayi bwe guba wansi w' ogwo ogusobola okulabibwa mu kukebera kuno.
5. Okulaga nti olina akawawuka so nga tolina kisobola okubaawo mu mbeera zino:
   Abalwadde nga beetabye mu kunoonyereza kw' ekisawo okw' eddagala erigema HIV.
6. Okubeerawo kw' akakuubo akageraageranyizibwako kitegeeza nti wabaddewo okutambula kw' ebigattiddwamu. Tekikakasa:
   - Ebikeberwa ebituufu bikozeseddwa.
   - Ebikeberwa biteereddwamu mu butuufu.
7. Nga bwe kiri ku kukebera okulala kwonna, ebiva mu kukebera tebirina kukakasibwa mu kukebera kwa mulundi gumu gwokka naye birina okukakasibwa omusawo ng' asinziira ne ku bivudde mu kukebera mu magezeserezo amalala. Ebifuniddwa mu Kwekebera kwa Wondfo okwa HIV tebirina kwesigamizibwako byokka.

EBIRAGA OBUTUUKAMU BW' ENKOLA

Mu kunoonyereza okw' ekisawo, abeetabi 900 abaali temanyiddwa oba balina HIV oba nedda baaweebwa Akakebera HIV aka Wondfo okwekebera. Ebyavaamu byageraageranyizibwa n' eby' omu ggezeserezo ery' omulembe ogwokuna. Ebyafunibwa mu ggezeserezo byalaga nti abeetabi abawera 77 baalina HIV, abeetabi 822 tebaalina HIV ate 1 teyamanyibwa. Abeetabi abawera 43 (5 balina HIV, 37 tebalina HIV nga 1 tamanyiddwa) tebassibwa mu kwekenneenya butuukamu. Okugeraageranya ebyavaamu kwali bwekuti:

- Abeetabi ebitundu 95.8% (69/72) baafuna ebyavaamu ebituufu nti balina akawuka. Kino kitegeeza nti abeetabi 3 abalina HIV baalagibwa nti tebalina kawuka. Kino kitegeeza abalina akawuka okulagibwa ng' abatakalina.
- Abeetabi ebitundu 4.7% (42/900) tebaasobola kumanyibwa bwe bayimiridde, ebikwata ku mwetabi 1 ku HIV tebyakakasibwa mu kunoonyereza kw' ekisawo noolwekyo tebyassibwa mu kwekenneenya.

BIWANDIIKO EBYAKOZESEBWA

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.

ENDAGIRIRO Y' OBUBONERO

IVD Akakeberera wabweru w'omubiri	Laba ebigobererwa mu kukozesa	Lwe kaggwaako
Mulimu ebimala okukebera emirundi <n>	Olunaku lwe kaakolebwa	Kabeere kakalu
LOT Nnambe y'ekitereke	Ekkomo ly'ebbugumu	Tereka wala ' n'omusana
Omukozi	Toddamu kukozesa	REF Ennamba y'akakebera
Okulabula	Tokozesa biri mu ccupa eno ssinga osanga nga ekisaanikira kisumuddwa omuntu omulala atali ggwe. Goberera endagiriro ekuwereddwa.	

Ebikwata ku mukozi

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Site web: en.wondfo.com

Tuukirira omukozi oba omutunzi mu ggwanga lyo bw' oba ng' olina ebibuuzo ebyekuusa ku kakebera kano.

Runyankore-Rukiga

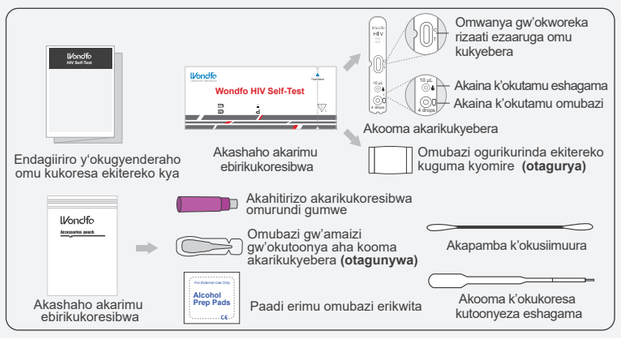
Wondfo HIV Self-Test

Endagiiriro y'okugyenderaho omu kukoresa ekitereko kya wondfo

- Nooteekwa kukuratira kurungi endagiiriro kubaasa kutunga rizaati ezihikire.
- Shutama omu mwanya omuyonjo kandi ogurimu ekyererezi kirikumara kandi oreebeke ngu oine byona ebirikwetengwa otakatandikire kwekyebera.
- Ekitereko eki nikikoresibwa omurundi gumwe gwonka. Otaigura akashaho akarimu akooma akarikukyebera waaba otakeeteebeekaniise ekirikumara.

Reeba vidiyo erikushoboorora enkoresa y' ekitereko

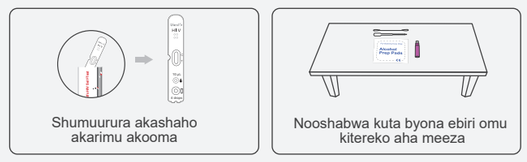
Contents



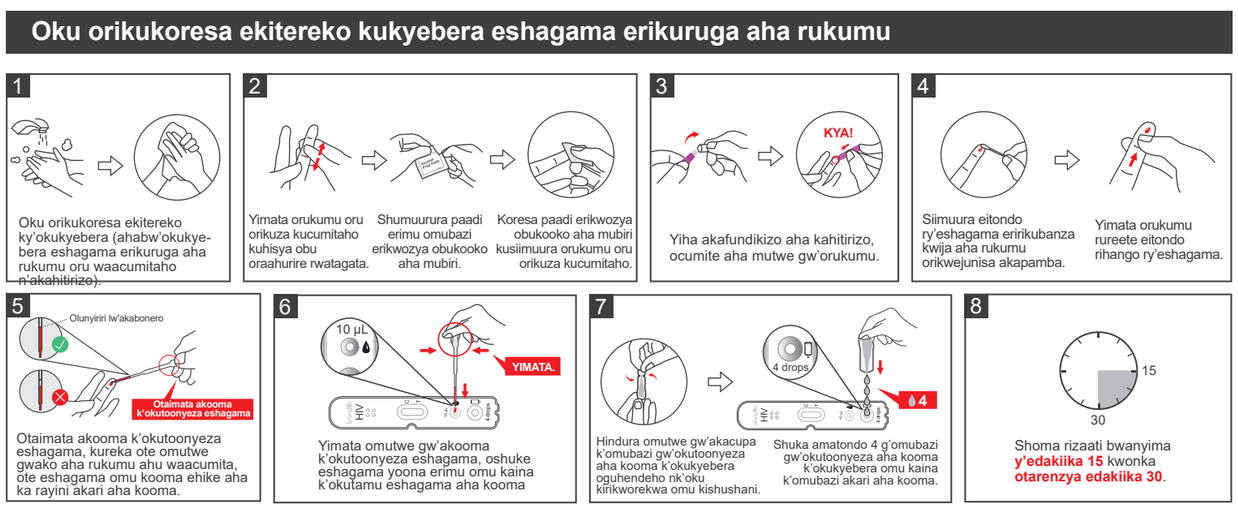
Hariho ebindi ebirikubaasa kwetengwa omu kukyebera kwonka bitarikwizira mu kitereko eki

Eshaaha | Obupapura bw'okwesiimuura | Bandegi

Okutebeekanisa



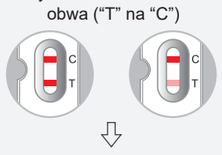
Oku orikukoresa ekitereko kukyebera eshagama erikuruga aha rukumu



Oku orikushoma rizaati ezaaruga omu kukyebera

Rizaati ezirikworeka ku oine akakooko ka siriimu

Oburayini bubiri oburi omu rangi obwa ("T" na "C")



Nooshabwa kuza omu irwariro aho naaho kwongyera kukyeberwa kuhamya rizaati.

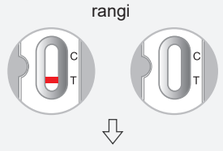
Rizaati ezirikworeka ku otaine kakooko ka siriimu.

Akarayini aka "T" kaaba katari mu rangi

Garuka oyekyebere bwanyima y'emyezi eshatu waaba ohikirweho ekintu kyona ekirikubaasa kukureetera kukwatwa akakooko ka siriimu omu bwire bukye obwenyima nainga waaba ori omu kabi kahango k'okukwatwa akakooko ka siriimu. Buuza abashaho omu irwariro erikuri haihi kumanya oburyo bw'okwerindamu akakooko ka siriimu.

Okukyebera okutaahika gye

Akarayini aka "C" kaaba katari mu rangi



Garuka oyekyebere nainga za omu irwariro erikuri haihi kwongyera kukyebeza kuhamya rizaati.

NAGA EBYAKORESIBWA

Byona ebi waakoresa omu kwekyebera binage omuri kasasiro kurugiirira aha biragiro by' omu kyanga kyawe ebirikukuratirwa omu kunaga ebintu ebirikubaasa kureeta oburwaire.

Ebibuuzo n'ebigarukwamu

1. Siriimu ni ki?

Obu n' oburwaire bw' omushagama oburikuza omu butafaari bw' omubiri oburikurwanisa oburwaire, oburikumanywa nka CD4. Akokooko ka siriimu ku karikuhika omu butafaari bw' omubiri katandika kuzaara kandi kaita obutafaari bw' omubiri ahu karikuzaarira. Omuntu oine akakooko ka siriimu yaaba atatungire mibazi erikuzibira akakooko ka siriimu kuzaara (ARV), amagara ge nigahwa amaani g' okutangira oburwaire kuhisya aha bwire obu gatarikubaasa kurwanisa oburwaire bwona.

2. Akakooko ka siriimu nikajanjaara kata?

Akakooko ka siriimu nikaza omu bicweka by' omubiri ebirimu eshagama, amaizi g' obushaija agarikushohora omu kuteerana, omu bicweka by' ekihama omu bakazi, n' amashereka omu mabeere. Akakooko ka siriimu nikabaasa kuruga omu muntu okaine kuza omu ndiijo kurabira omu miringo egi:

- Okuteerana kw' abashaija n' abakazi nainga okw' ebitingwa omwe omuri bo yaaba aine akakooko ka siriimu, baaba batakoreise bupiira nainga obumwe omu kukoresa orurimi n' akanwa omu kuteerana.
- Okuta eshagama erimu akakooko ka siriimu omu muntu otakaine.
- Okukoresa empitirizo, ebomba z' ebikatu nainga ebintu ebindi ebikoresiibwe omuntu oine akakooko ka siriimu.
- Omukazi orikwonsya yaaba aine akakooko ka siriimu naaba kukaturira mwana we omukazi yaaba aine enda, yaaba naazaara nainga yaaba naayonsya.

Omuntu oine akakooko ka siriimu yaaba naakoresa emibazi erikuzibira akakooko ka siriimu kweyongyera omu mubiri erikumanywa nka ART (Antiretroviral therapy) erikukyendeereza kimwe akakooko ka siriimu omu mubiri, emigisha y' omuntu ogwe kuturira abandi akakooko ka siriimu neekyendeerera kimwe.

3. Ni ryari obu nshemereire kwekyebera akakooko ka siriimu?

Abantu abahikirweho embeera yoona erikubaasa kubareetera kukwatwa akakooko ka siriimu omu bwire bukye obwenyima nainga amagara gaabo gaaba gari omu kabi k' okubaasa kukwatwa akakooko ka siriimu bashemereire kwekyebeza. Emiringo y' okukyebera akakooko ka siriimu erikukira kukoresibwa neekyebera kumanya yaaba omubiri gwinemu obutafaari bw' okurwanisa akakooko ka siriimu. Obwire obwingi, emibiri y' abantu neekora obutafaari bw' okurwanisa akakooko ka siriimu omu biro 28 bwanyima y' okukwatwa akakooko ka siriimu. Omuntu yaakyebeza omu bwire obu arikukoresa emiringo y' okukyebera erikukyebera obutafaari bw' omubiri oburikurwanisa akakooko ka siriimu, naabaasa kutunga rizaati ezigwire, ezirikworeka ku ataine kakooko ka siriimu. Nobu abantu abari omu kabi k' okukwatwa akakooko ka siriimu bashemereire kwekyebeza ahonaaho, rizaati ezirikworeka ku bataine ka kakooko ka siriimu ezirikutungwa omu biro 28 zishemereire kuhamibwa bwanyima y' okugarukamu kwekyebeza hahwaireho emyezi eshatu.

4. Nshemereire kukora ki rizaati zaayoreka ku nyine akakooko ka siriimu?

Oshemereire kureeba omushaho kwongyera kukukyebera kuhamya rizaati ezi waatunga. Aha bwire obwo, abashaho b' omu kyanga kyawe nibaija kukuhabura eki oshemereire kukuratsaho.

Ebirikwata aha kitereko

ENAMBA Y' EKITEREKO.

W006P0058 W006P0059 W006P0060

OMUGASHO GW' EKITEREKO

Wondfo n' ekitereko ekirikwejunisibwa omu kwekyebera akakooko ka siriimu, kandi nikikoresibwa omurundi gumwe. Omu kukoresa ekitereko eki, omuntu naacumita aha mutwe gw' orukumu rwe kukyebera eshagama kumanya yaaba aine akakooko ka siriimu ak' ekika kya HIV-1/2. Kikozirwe n' ekigyendererwa ky' okuhwera omuntu kwekyebera nainga kukoresibwa abashaho abatendekirwe.

Ekitereko nikikoresibwa kukyebera eshagama yonka.

EBIRIKUKURATIRWA OMU KWEKYEBERA

Ekitereko kya Wondfo HIV Self-Test nikikuratira enkora y' okukyebera obutafaari bw' omushagama. Ku orikuta eshagama omu kaina akari aha kooma n' omubazi ogurikutabura eshagama omu kaina aka kabiri aha kooma, nibiija kutambura omu kooma kurabira omu kashekye akarimu. Obutafaari bw' omu shagama oburikurwanisa akakooko ka siriimu ak' ekika kya HIV-1 n' aka HIV-2 nainga bwombi bwaba buri omushagama nibwekwata aha mwanya ogurikukyebera aha mwanya oguriho enyuguta (T) aha kooma akarikukyebera. Obutafaari oburikurwanisa akakooko ka sirimu ak' ekika kya HIV-1 n' aka HIV-2 nainga bwombi bwaba buri omu shagama nibukora erangi aha mwanya (T) aha kooma ekirikumanyisa ngu orikukyeberwa aine akooko ka siriimu. Obutafaari oburikurwanisa akakooko ka sirimu ak' ekika kya HIV-1 n' aka HIV-2 nainga bwombi bwaba butari mu shagama erangi terikwija kureebekyera aha mwanya (T) aha kooma ekirikumanyisa ngu orikukyeberwa taine kooko ka siriimu. Erangi erikureebekyera aha mwanya (C) neeyoreka ku okukyeberwa kwakorwa kurungi.

OKWEGYENDESEREZA N' OKUHABURA

Otakoresa ekitereko ebiro ebikihairwe kukoresizibwamu byaba byahwireyo.
Otakoresa ekitereko akashaho kaaba kafumwireho nainga katasibire gye.
Otakoresa ekitereko kwekyebera waaba otakahikize myaka 12 y' obukuru.
Otakoresa ekitereko kwekyebera waaba noojwa munonga eshagama waaheza kuhutaara.
Otakoresa ekitereko kwekyebera waaba waareekyebeizeho okashanga oine akakooko ka siriimu.
Otashumuurura ekitereko waaba otakeetebeekaniise kurungi kwekyebera.
Naaba omu ngaro kandi oreebe ngu zaayera kurungi kandi zaayoma otakatandikire kwekyebera.
Nooyetenga ekyererezi kirikumara kukuhwera kushoma kurungi rizaati ezaaruga omu kukyebera.

EBIRIKWIZIRA OMU KITEREKO

Hariho emiringo eshatu y' ebitereko egi; omuringo ogurimu ekitereko ky' okukyebera omurundi gumwe, omuringo ogurimu ebitereko eby' okukyebera emirundi 20 hamwe n' omuringo ogurimu ebitereko eby' okukyebera emirundi 100. Ebirikwizira omu kitereko nibyorekwa ahaifo:

Ebiri omu kitereko \ Catalog No.		W006P0058	W006P0059	W006P0060
Akashaho akarimu akooma k' okukyebera	Akooma k' okukyebera	1	1x20	1x100
	Omubazi gw' okwomya ekitereko	1	1x20	1x100
Ebindi ebirikwizira omu kitereko	Akooma k' okutoonyeza eshagama	1	1x20	1x100
	Omubazi gw' okutoonyeza	1	1x20	1x100
	Orupapura rurikworeka enkozesa y' ekitereko	1	1x20	1x100
	Akahitirizo	1	1x20	1x100
	Paadi erimu omubazi	1	1x20	1x100
	Akapamba	1	1x20	1x100
	Ashaho k' okunagiramu ekitereko ahanyima y' okukikoresa	1	/	/

Akooma k' okukyebera karimu emibazi erikwetengyesa kureeba obutafaari bw' omubiri oburikurwanisa akakooko ka siriimu omu shagama n' emibazi erikworeka yaaba okukyebera kwakorwa gye.

OBURYO BW' OKUBIIKAMU EKITEREKO

1. Ekitereko kibiike omu butagasi oburi ahagati ya 2-30 °C kumara emyezi 24.
2. Akooma akarikukyebera kakorese obutarezya eshaaha 1 waaheza kukashumuurura.
3. Ekitereko kitaza aha mushana, kitahikwa amaizi n' ekyoya.
4. Koresa ekitereko omu butagasi oburi ahagati ya 10-30 °C.

EBI EKITEREKO KIGYENDEREIRE KUKORA

1. Ekitereko kikozirwe kukyebera eshagama erugire aha rukumu.
2. Ekitereko nikikyebera obutafaari bw' omubiri oburi omu shagama oburikurwanisa akakooko ka siriimu ak' ekika kya HIV-1 na HIV-2.
3. Ebishemereire kukuratirwa omu kukoresa ekitereko n' okushoma rizaati bishemereire kukuratirwa kurungi. Okutunga rizaati ezihikire, nooteekwa kukuratira kurungi oburyo bw' okutunga eshagama y' okukyebera. Waaremwa kukuratira kurungi enkozesa, noobaasa kutunga rizaati zitahikire.
4. Rizaati ezirikworeka ku omuntu ataine kakooko ka siriimu ezitahikire nizibaasa kurugiirira aha nshonga ezi:
   - Abantu baaba bakwasirwe akakooko ka siriimu omu bwire obutarikurenga myezi 3.
   - Abarwaire baaba nibatunga emibazi y' okukyendeeza akakooko ka siriimu omu mubiri (Antiretroviral therapy).
   - Obutafaari oburikurwanisa akakooko ka siriimu omu shagama bwaba buri bukye munonga butarikubaasa kukwatwa akooma akarikukyebera.
5. Rizaati ezirikworeka ku omuntu aine kakooko ka siriimu kandi atakaine nizibaasa kurugiirira aha nshonga ezi:
   - Abantu baaba beejumbire omu kugyezesa emibazi erikugyema akakooko ka siriimu.
6. Erangi erikwija aha karayini akari ahari (C) nikamanyisa ngu omubazi gwateebwa aha kooma. Eki tikirikumanyisa ngu:
   - Eshagama eyaakoresibwa ekihikire.
   - Eshagama yaateebwa aha kooma omu muringo guhikire.
7. Nk' oku okukyebera eshagama kwona kuri, torikuhamya rizaati ezaakorwa omurundi gumwe ku omuntu aine oburwaire kureka omushaho niwe ashemereire kukihamya kurugiirira aha bi yaakyebera na rizaati ezaaruga omu kukyebera okundi okwakorerwa omu raabu. Rizaati ezirikuruga omu kitereko kya Wondfo HIV Self-Test tizishemereire kwemariirira zonka kuhamya ku omuntu aine akakooko ka siriimu.

EBYARUGIRE OMU KUGYEZESA EKITEREKO

Omu kucondooza okwakozirwe, abantu 900 abaabaire batarikumanya yaaba baine akakooko ka siriimu nainga batakaine bakaheebwa ebitereko bya Wondfo HIV Self-Test kwekyebera. Rizaati zikagyeragyeranisibwa n' ezo ezaarugire omu kukyebera okwakoreirwe omu raabu. Rizaati ezaarugire omu raabu zikooreka ku abantu 77 omuri abo abayejumbire omu kucondooza bakaba baine akakooko ka siriimu, abantu 822 bakaba batakaine, kandi omuntu omwe rizaati zikaba zitoorekire ekyarugire omu kucondooza. Rizaati z' abantu 43 (ez' abantu 5 abaine akakooko ka siriimu, ez' abantu 37 abataine kakooko ka siriimu n' ez' omuntu 1 ou rizaati zitaine eki zaayorekire) tizirashwijumirwe. Ebyarugire omu kugyeragyeranisa rizaati n' ebi ahaifo:

- Ebicweka 95.8 ahari 100 by' abantu abaayejumbire omu kucondooza (abantu 69 ahari 72) bakatunga rizaati ezihikire gye bwanyima y' okwekyebera zikworeka ku baine akakooko ka siriimu. Eki nikimanyisa ngu abantu 3 abaabaire baine akakooko ka siriimu bakatunga rizaati ezirikworeka ku batakaine. Eki nikimanywa nk' okutunga rizaati zirikworeka ku omuntu ataine burwaire kandi abwine.
- Ebicweka 99.6 ahari 100 by' abantu abaayejumbire omu kucondooza (abantu 782 ahari 785) bakatunga rizaati ezihikire gye bwanyima y' okwekyebera rizaati zikooreka ku bataine kakooko ka siriimu. Eki nikimanyisa ngu abantu 3 abaabaire bataine kakooko ka siriimu bakatunga rizaati zirikworeka ku bakaine Eki nikimanywa nk' okutunga rizaati zirikworeka ku omuntu aine aine oburwaire kandi atabwine.
- Ebicweka 4.7 ahari 100 (abantu 42 ahari 900) bakaremwa kutunga rizaati, omwe omuribo rizaati ze tizirabaasize kuhamibwa omu kushwijuma. Nahabwekyo, rizaati ze tizirashwijumirwe.

EBIHANDIIKO EBIKORESIIBWE

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.

AMAKURU G'OBUMANYISO OBUKORESIIBWE

IVD Akooma k'okukyebera eshagama	Reeba aha birikukuratirwa omu kukoresa ekitereko	Ebiro ebi kitashemereire kurengaho kitakakoresibwe
Ebirimu nikoresibwa emirundi <-->	Ebiro obu kyaakorwa	Kirinde kigume kyomire
LOT Batch code	Otarenzya aha butagasi obu	Kitahikwa omushana
Kampuni yaakikozire	Otakikoresa omurundi ogundi	REF Enamba y'ekitereko
Yegyendesereze ebi	Otakoresa ekitereko waashanga kishumurwire. Kuratira endagiiriro oku orikubaasa kukikoresa.	

Amakuru agarikuktwata aha kampuni yaakikozire

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Tuukirira omukozi oba omutunzi mu ggwanga lyo bw' oba ng' olina ebibuuzo ebyekuusa ku kakebera kano.

ENGLISH

Rev. A7 Rel.: 2023/03/31

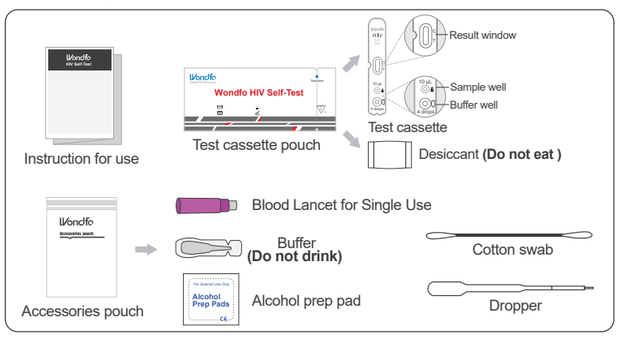
Wondfo HIV Self-Test

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

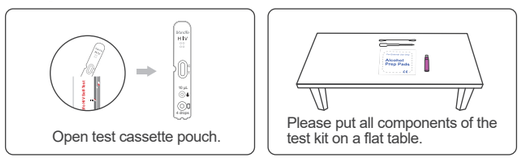
Contents



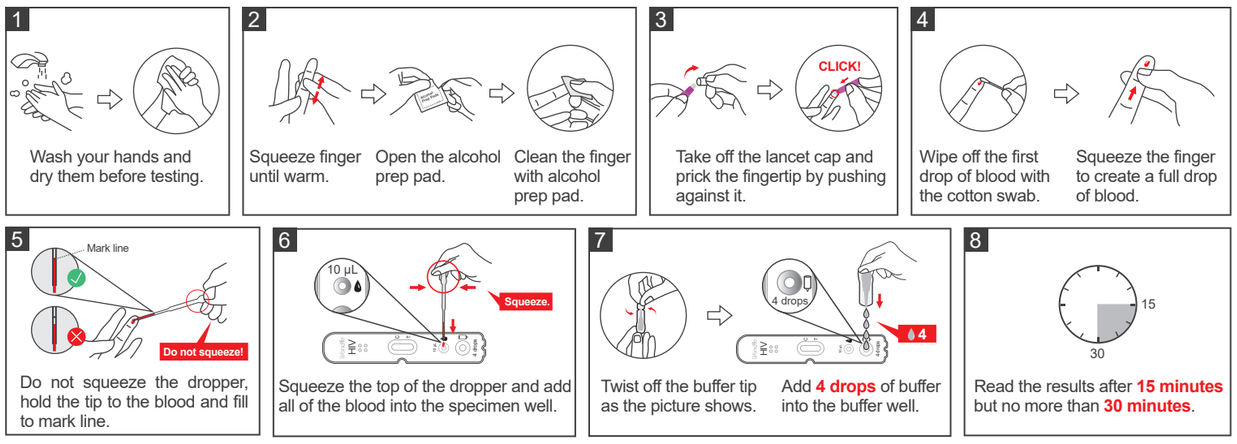
Materials may be required but not provided.

Timer Tissue Bandage

Preparation



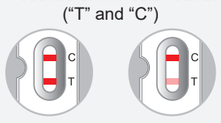
How to use the test kit (for fingerstick whole blood use)



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.

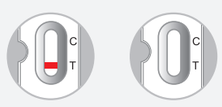
Negative (-)

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

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		Use-by date
Σ	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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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.

Shona

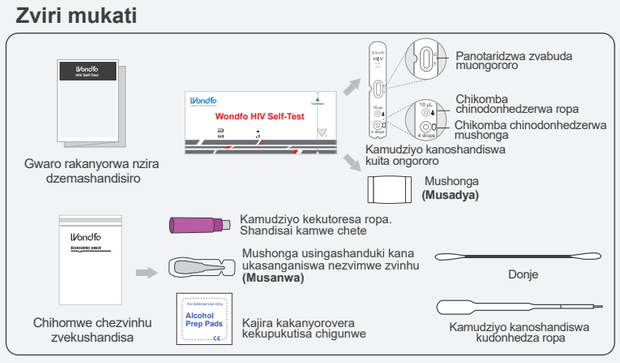
Wondfo HIV Self-Test

Zvamunofanira kuita

- Tevedzerai tsananguro yemaitirwo eongororo. Izvi zvinobatsira kuti muwane mhinduro yakafanira pakuongororwa kweropa.
- Garai panzvimbo yakachena, ine chiedza chakakwana. Ivai nechokwadi chekuti mune zvose zvinofanira kushandiswa musati matanga kuita ongororo.
- Shandisai kamwe chete. Musavhura chihomwe chine kamudziyo kanoshandiswa kuita ongororo kana musati magadzikana.

Onai vhidhiyo yemaitirwo eongororo

Zviri mukati



Zvinhu zvinoshandiswa asi zvinogona kunge zvisipo

Wachi Tishu Bhandeji

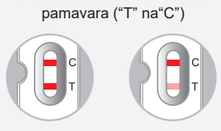
Gadziriro

Mashandisirwo ezviri muchihomwe chezvinoshandiswa pakuita ongororo (pakutora ropa pamunwe)

Tsananguro yezvabuda muongororo

Kana mune utachiwana

Panobuda mitsetse miviri iri pamavara (“T” na“C”)



Endai kukirinika kuti mundoongororwa zvakare nokukasira kose kunogoneka.

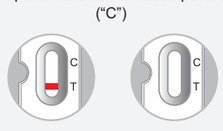
Kana musina utachiwana

Hapana mutsetse unobuda pavara (“T”)

Dzokororai kuita ongororo mumwedzi mitatu kana makaita bonde risina kudzivirirwa munguva shoma yadarika kana kuti muri panjodzi huru yekutapukirwa neutachiwana. Bvunzai nezvekudzivirirwa kweHIV pakirinika iri pedo nemi.

Kana ongororo isina kubuda zvakanaka

Hapana mutsetse unobuda pavara (“C”)



Itai imwe ongororo kana kuti endai kukirinika mundoongororwa zvakare.

KURASA TSVINA

Rasai zvose zvamashandisa mubhini remarara. Rasai muchitevedza mitemo yenyika inotevedzwa pakurasa tsvina inogona kutapurira vanhu zvirwere.

Mibvunzo nemhinduro

1. Chii chinonzi HIV?

Utachiwana hwehuman immunodeficiency virus (HIV) hunorwisa masoja anorwisa zvirwere mumuviri anonzi CD4. Kana hukapinda mukati memasoja anorwisa zvirwere mumuviri eCD4, utachiwana hweHIV hunowanda. Izvi zvinokuvadza nokuparadza masoja aya. Kana utachiwana hukasanyatsorapwa nemubatanidzwa wemishonga inorwisa HIV, masoja anorwisa zvirwere mumuviri anopera simba zvekusvika pakutadza kurwisa utachiwana nezvirwere.

2. HIV inotapuriranwa sei?

Utachiwana hweHIV hunowanikwa muropa, mvura inogara urume, mvura dzemusikarudzi yemunhukadzi, mvura dzekumashure nemumukaka waamai. HIV inogona kutapuriranwa kuburikidza ne:

- Kuita bonde risina kuchengetedzwa rinoitwa kuburikidza nesikarudzi yemunhukadzi kana kuti nekumashure, uye, nenguva dziri kure, kuburikidza nebonde rinoitwa nemuromo nemunhu anorarama neutachiwana hweHIV.
- Kuwedzerwa ropa rine utachiwana.
- Kushandisa tsono, masirinji, midziyo yekubaya nayo majekiseni, midziyo yekuvhiya vanhu nayo kana kuti mimwe midziyo yakapinza yakamboshandiswa nemumwe.
- Kubva kuna amai vanorarama neutachiwana hweHIV kuenda kumwana ari mudumbu pangu-va yekuzvitakura, pakuzvara kana kuti pakuyamwisa.

Kana munhu anorarama neutachiwana hweHIV akanwa mishonga inonyatsorwisa utachiwana uhwu mumuviri, mukana wake wekutapurira HIV kune vamwe unoderera zvikuru.

3. Ndinofanira kuzviongorora kana zvaita sei?

Vanhu vanenge vaita bonde risina kuchengetedzwa kana kuti vari panjodzi yekutapukirwa neHIV vanofanira kuongororwa. Ongororo dzinonyanyoshandiswa kuongorora utachiwana hweHIV dzinotarisa masoja anorwisa zvirwere mumuviri anoburitswa nemuviri pakurwisa HIV. Nguva zhinji, muviri wemunhu unogadzira masoja anorwisa HIV mukati memazuva makumi maviri nemasere ekutapukirwa neutachiwana. Panguva iyi, ongororo yeutachiwana inogona kutaridza kuti munhu haana utachiwana asi iwo ari manyepo. Chero zvazvo vanhu vari panjodzi yekutapukirwa neHIV vachifanira kuongororwa nekukasira, kana ongororo inenge yaitwa mukati memazuva makumi maviri nemasere ekuita bonde risina kuchengetedzwa ikataridza kuti munhu haana utachiwana, anofanira kuita imwe ongororo mwedzi mitatu isati yadarika.

4. Chii chandinofanira kuita kana ongororo ikataridza kuti ndine utachiwana?

Munofanira kuenda kumushandi wezveutano kuti muitwe imwe ongororo. Vepakirinika penyu vachakuzivisai zvamunofanira kuita.

Ruzivo ruri maererano nekamudziyo kanoshandiswa kuongorora HIV

NHAMBA YERUPAWO

W006P0058 W006P0059 W006P0060

MASHANDISIRWO ANOTARISIRWA

Wondfo HIV Self-Test kamudziyo kanoshandiswa kuzviongorora utachiwana hweHIV-1/2 paropa rinotorwa pamunwe. Kamudziyo aka kanoshandiswa kamwe chete. Kanogona kushandiswa nemunhu kuzviongorora kana kuti nanachiremba nanamukoti.

Kamudziyo aka kanoshandiswa paongororo inoitirwa kunze kwemuviri chete.

ZVINOFANIRA KUITWA PAONGORORO

Wondfo HIV Self-Test inzira yekudonhedzera ropa nemushonga unenge waiswa mariri pakamudziyo kanoshandiswa kuongorora utachiwana hweHIV. Kana ropa nemushonga zvikai-swa muzvikomba zvakakodzera, zvinoerera zvega pakamudziyo kanoshandiswa kuita ongoro-ro aka. Masoja emuviri anorwisa HIV-1 uye/kana kuti HIV-2 anobatira pautachiwana hweHIV (gp36/41) uye mubatanidzwa uyu unozobatwa neutachiwana hweHIV (gp41 negp36) panzvim-bo ine vara (T) pakamudziyo kanoshandiswa kuita ongororo. Kana uwandu hwemasoja anor-wisa utachiwana hweHIV-1 kana kuti hweHIV-2 mumuviri hukasvika kana kuti kudarika chipi-mo chinotarisirwa paongororo, panobuda kamutsetse kane ruvara panzvimbo ine vara (T) kutaridza kuti mune utachiwana. Kana uwandu hwemasoja anorwisa utachiwana hweHIV-1 kana kuti hweHIV-2 mumuviri huri pasi pechipimo chinotarisirwa paongororo kana kuti pasina masoja aya zvachose, hapana mutsetse une ruvara unobuda panzvimbo ine vara (T), kutarid-za kuti hamuna utachiwana. Kana zvadaro, mutsetse une ruvara unobuda panzvimbo ine vara (C).

CHENJEDZO

Musashandisa kamudziyo kanoshandiswa kuita ongororo kana mazuva ekushandiswa kwako adarika.
Musashandisa kamudziyo aka kana chihomwe chacho chakabooka kana kuti chisina kuvharwa nemazvo.
Musashandisa kamudziyo aka kana une makore ekuberekwa ari pasi pegumi nemaviri.
Musashandisa kamudziyo aka kana mune dambudziko rekubuda ropa.
Musashandisa kamudziyo aka kana makamboongororwa zvikaonekwa kuti mune utachiwana hweHIV.
Musavhura chihomwe chinochengeterwa kamudziyo aka kusvika magadzirira kuita ongororo iyi.
Gezai maoko enyu anyatsochena mugoaomesa musati matanga kuita ongororo.
Panodiwa chiedza chakajeka kuti mukwanise kuverenga zvinenge zvabuda muongororo.

ZVINOSHANDISWA PAKUITA ONGORORO

Kune mapoka matatu ezvinoshandiswa pakuita ongororo. Boka rekutanga nderinoshandiswa kuita ongororo imwe chete. Rechipiri rinoshandiswa kuita ongororo makumi maviri uye rechita-tu rinoshandiswa kuita ongororo zana. Zvinoshandiswa pakuita ongororo zvakatsanangurwa pazasi apa:

Zviri mukati \ nhamba yerupawo		W006P0058	W006P0059	W006P0060
Chihomwe chekamuziyo kanoshandiswa kuita ongororo	Kamuziyo kanoshandiswa kuita ongororo	1	1x20	1x100
	Mushonga	1	1x20	1x100
Zvekushandisa	Kamudziyo kanoshandiswa kudonhedza ropa	1	1x20	1x100
	Mushonga usingashanduki kana ukasanganiswa nezvimwe zvinhu	1	1x20	1x100
	Gwaro rakanyorwa nzira dzemashandisiro	1	1x20	1x100
	Kamudziyo kekutoresa ropa kanoshandiswa kamwe chete	1	1x20	1x100
	Kajira kakanyorovera kekupukutisa chigunwe	1	1x20	1x100
	Donje	1	1x20	1x100
	Chihomwe chekurasira tsvina	1	/	/

Kapepa kamwe chete kanoshanduka kana kakaiswa mushonga kane zvinotevera: Gold conju-gate (Utachiwana hweHIV hwakabatana nemushonga unomutsa masoja anorwisa utachiwana mumuviri), Mutsetse unotaridza kuti mune utachiwana here kana kuti kwete (Mishonga inomut-sa masoja anorwisa zvirwere mumuviri) neMutsetse unotaridza kuti ongororo iri kufamba zvakanaka here (mhando dzakasiyana dzemasoja anorwisa zvirwere mumuviri emhando yeGoat anti rabbit IgG).

MACHENGETERWO EMIDZIYO YEONGORORO

1. Chengeterai zvinoshandiswa pakuita ongororo iyi panzvimbo inodziya zviri pakati pe2° C ne 30°C kwemwedzi makumi maviri nemina.
2. Shandisai kamuziyo kanoshandiswa kuita ongororo mukati meawa imwe chete kubva pamu-novhura chihomwe chacho.
3. Musachengetera panzvimbo ine chiedza chezuva, unyoro kana kuti panopisa.
4. Shandisai kamudziyo aka panzvimbo inodziya zviri pakati pe10°C ne30°C.

ZVINOTARISIRWA PAONGORORO

1. Ongororo iyi yakagadzirirwa kuti ishandise ropa remunhu rinotorwa pamunwe.
2. Ongororo iyi inoshandiswa pakutarisa masoja emuviri anorwisa HIV-1 neHIV-2 chete.
3. Matorerwe eropa nekutsanangurwa kwezvinenge zvabuda muongororo zvinofanira kunyatsoitwa nemazvo. Kuti ongororo ibude zvakanaka, ropa rinofanira kutorwa nemazvo. Kutadza kutevedza mashandisirwo ezvinhu kunokonzera kuti ongororo isabuda zvakanaka.
4. Ongororo inogona kutaridza kuti hapana utachiwana asi iwo ari manyepo:
   - Kana varwere vakatapukirwa neutachiwana hweHIV munguva iri pasi pemwedzi mitatu yadarika.
   - Kana varwere vari kushandisa mishonga inorwisa utachiwana hweHIV.
   - Kana uwandu hwemasoja emuviri anorwisa HIV ari muropa rinenge ratorwa huri pasi pehunokwanisa kuonekwa paongororo.
5. Ongororo inogona kutaridza kuti pane utachiwana asi ari manyepo:
   - Kana varwere vakambopinda mutsvakurudzo yekutsvaka mushonga wekudzivirira utachiwana hweHIV.
6. Kamutsetse kanotaridza kuti ongororo iri kufamba zvakanaka here kanongoreva kuti ropa nemishonga zvinenge zvaerera kubva pane imwe nzvimbo kuenda pane imwe. Hachisi chivimbiso chekuti:
   - Ropa nemishonga zvashandiswa ndizvo zvakakodzera.
   - Ropa nemishonga zvashandiswa nemazvo.
7. Sezvinongoitika paongororo dzose dzine chekuita nezvekurapwa, vanhu havafaniri kutambira zvinenge zvabuda muongororo imwe chete sechokwadi; vanofanira kuita dzimwe ongororo nemushandi wezveutano murabhoritari. Zvinenge zvabuda paongororo yekuviongorora HIV yeWondfo HIV Self-Test hazvifaniri kutambirwa zviri zvega pasina kuitwa dzimwe ongororo.

ZVAKABUDA PANE VAKAMBOSHANDISA KAMUDZIYO KEKUONGORORA HIV AKA

Mutsvakurudzo yezvekurapwa, vanhu mazana mapfumbamwe vakange vasingazivikanwi kuti vane HIV here kana kuti kwete vakapiwa kamudziyo keWondfo HIV Self-Test kuti vazvion-gorore. Zvakabuda muongororo zvakaenzaniswa nezvakabuda muongororo yemurabhoritari. Zvakabuda muongororo yemurabhoritari zvakataridza kuti vanhu makumi manomwe nevanom-we vakange vari mutsvakurudzo vakange vane utachiwana hweHIV, mazana masere nemaku-mi maviri nevaviri vakange vasina utachiwana uye mumwe chete haana kuzivikanwa kuti ane utachiwana here kana kuti kwete. Vanhu makumi mana nevatatu vakange vari mutsvakurudzo (vashanu vakange vane utachiwana hweHIV, makumi matatu nevanomwe vakange vasina utachiwana uye mumwe chete haana kuzivikanwa kuti ane utachiwana here kana kuti kwete) vakabviswa paongororo yemashandiro ekamudziyo aka. Kuenzaniswa kwezvakabuda muon-gororo idzi kwakataridza zvinotevera:

- Chikamu che95.8% chevakange vari mutsvakurudzo (vanhu makumi matanhatu nevapfum-bamwe kubva mumakumi manomwe nevaviri) vakakwanisa kuita ongororo yakataridza kuti vaiva neutachiwana. Izvi zvinoreva kuti vanhu vatatu vaiva mutsvakurudzo vaiva neutachiwa-na hweHIV vakaita ongororo dzakataridza kuti havana utachiwana. Idzi iongororo dzinotarid-za kuti hapana utachiwana asi iwo ari manyepo.
- Chikamu che99.6% chevakange vari mutsvakurudzo (vanhu mazana manomwe nemakumi masere nevaviri kubva mumazana manomwe nemakumi masere nevashanu) vakakwanisa kuita ongororo yakataridza kuti vakange vasina utachiwana. Izvi zvinoreva kuti vanhu vatatu vaiva mutsvakurudzo vakange vasina utachiwana hweHIV vakaita ongororo dzakataridza kuti vane utachiwana. Idzi iongororo dzinotaridza kuti pane utachiwana asi iwo ari manyepo.
- Chikamu che4.7% chevakange vari mutsvakurudzo (vanhu makumi mana nevaviri kubva mumazana mapfumbamwe) vakaita ongororo dzisina chadzakabudisa, ongororo dzakaitwa pamunhu mumwe chete aiva mutsvakurudzo dzakatadza kuona kuti aiva neutachiwana here kana kuti kwete, nokudaro haana kuverengwa paongororo yakaitwa.

JERERO

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.

MIFANANIDZO NEZVAINOREVA

IVD	Mudziyo weongororo yezvekurapwa inoitirwa kunze kwemuviri		Tarisai gwaro rakanyorwa nzira dzemashandisiro		Zuva rekupedzisira rekushandiswa kwemudziyo uyu
Σ	Mune zvinokwana zvinodikanwa pakuita ongororo		Zuva rakagadzirwa mudziyo uyu		Chengeterai pasina unyoro
LOT	Nhamba yerupawo rwemudziyo iyi		Muganhu wekudziya kwemhepo		Musachengetera pane chiedza chezuva
	Vagadziri vemudziyo uyu		Musadzokororo kushandisa zvakare	REF	Nhamba yerupawo rwemudziyo uyu
	Chenjedzo		Usaita zvakadaro kana paketi iri kugadziriswa nokugadzirisa kunzwisisa pamaitiro ekushandiswa kwacho		

Ruzivo maererano nevagadziri vemudziyo uyu

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Kana mune mibvunzo chero ipi zvayo maererano nemudziyo uyu, zivisai vagadziri vawo kana kuti vanoutengesa munyika menyu.

Ndebele

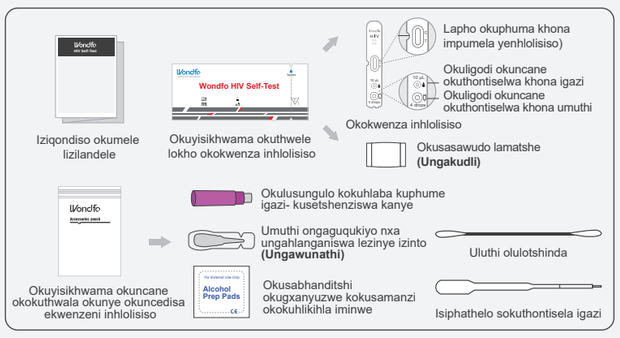
Wondfo HIV Self-Test

Iziqondiso okumele lizilandele

- Kumele ulandele kuhle indlela yokwenza inhlolisiso ukuze uthole impumela eqondileyo yokuhlolwa kwegazi.
- Hlala endaweni ehlanzekileyo ekhanyayo kahle uqinisike lokuthi ulakho konke okudingekayo andubana uqale umsebenzi wokuzihlola.
- Sebenzisa kanye kuphela. Ungavuli okuyisikhwama okuthwele lokho okokusebenzisa ukwenza inhlolisiso uze ube usulungele ukwenza inhlolisiso.

Bukela ividiyo emayelana lokuqhutshwa kwenhlolisiso

Okuphakathi

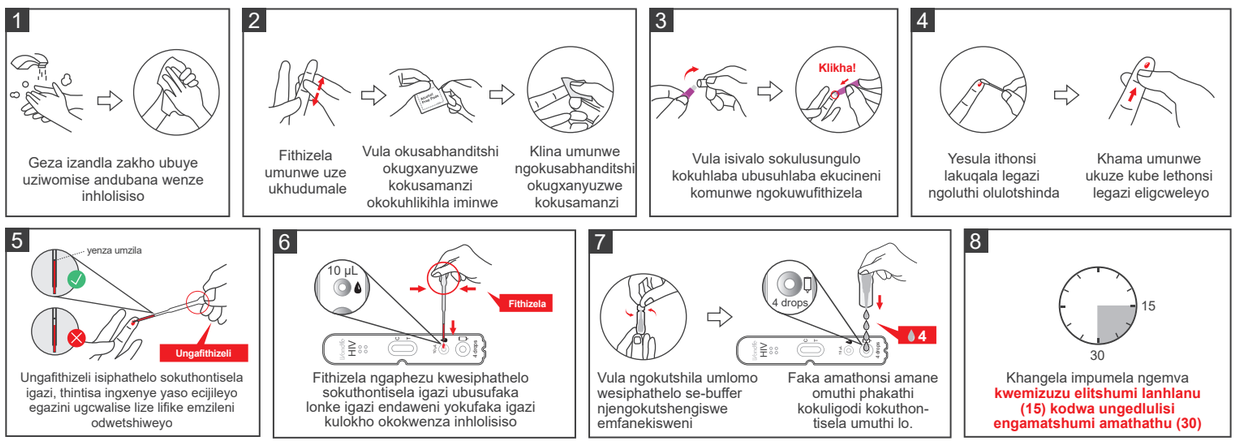


Okokusebenzisa okungadingakala kodwa okungekho phakathi la

Iwatshi | Ithishu | Ibhanditshi

Amalungiselelo

Indlela yokusebenzisa lokho okusesikhwameni okokwenza inhlolisiso (ngeyokuhlaba umunwe kuthathwe igazi linjalo lingahluzwanga)



Ukubala impumela yenhlolisiso

Ukubakhona kwegcikwane le-HIV (Ukuba-positive)

Nxa ulegcikwane kubonakala ngemizila emibili elemibala (omunye uqondana lo “T” omunye lo “C”)

Yana eklinika ngokuphangisa uyethola inhlolisiso yokuqiniseka.

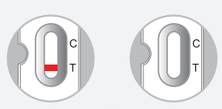
Ukungabikhona kwegcikwane le-HIV (Ukuba-negative)

Nxa ungelagcikwane kuyabe kungelamzila olombala maqondana lo-“T”.

Hlola njalo ngemva kwenyanga ezintathu nxa uke wabasengozini ye-HIV esikhathini esisanda kwedlula kumbe loba usengozini ephezulu yokubamba igcikwane le-HIV. Buza mayelana lokukhona okokwenqabela i-HIV eklinika esesduzane lawel

Inhlolisiso engaphumanga kuhle

Ukungabikhona komzila olombala oqondane lo-“C”



Yenza eyinye inhlolisiso kumbe uye eklinika ukuze uyethola inhlolisiso yokuqinisekisa.

UKULAHLA INGCEKEZA

Lahla konke okusetshenziswayo ezibini zansukuzonke loba ulahle ulandela imithetho leziqondiso eziphathelane lokulahla izibi ezilakho ukubangela imikhuhlane yokuthelelwana.

IMIBUZO KANYE LEMPENDULO

1. Iyini i-HIV?

Igcikwane le-HIV lihlasela izakhamzimba ezivikela umzimba ezibizwa ngokuthi CD4 zona ezisiza umzimba ekulwiseni izifo. Igcikwane leli liyazalana libuye lilimaze phakathi kwama-CD4. Nxa kungela kwelatshwa okuzwayo ngemihlobo yama-ARV ehlanganisiweyo amasotsha omzimba ayaphela amandla kuze kufike ebangeni lokuthi awasenelisi ukulwisa izifo lokubangela izifo.

2. I-HIV ithelelwana njani?

I-HIV itholakala egazini, enhlanyelweni yabobaba, okungamanzi okuphuma emphumelweni kanye lasechagweni lwamabele ebantwini abalegcikwane le-HIV. I-HIV ingathelelwana ngoku:

- Hlangana emacansini okusetshenziswa isitho sangaphansi sabomama kumbe umphumelo njalo ngevelakanci ngamacansi enziwa ngomlomo lomuntu olegcikwane le-HIV.
- Fakwa igazi elilegcikwane.
- Kusebenziselana inalithi, amajekiseni lokunye okokuzihlaba, okusetshenziswa ekuhlinzeni abantu loba nje okunye okucijileyo okuhlabayo.
- Sukela kumama ole-HIV kusiya esaneni ngesikhathi sokuzithwala, sokubeletha loba ukumunyisa.

Nxa umuntu ephila legcikwane le-HIV enatha ama-ARV wona asebenzayo, ithuba lakhe lokuthelela omunye liyehla kakhulu.

3. Kunini lapho okudingeka ukuthi ngizihlole khona?

Abantu asebeke babasengozini ye-HIV loba abasengozini ye-HIV kumele badinge ukuhlolwa. Inhlolisiso ezisetshenziswa kakhulu zidinga amabutho avikela umzimba njengendlela yawo yokulwisa i-HIV. Kanengi, abantu baba lamabutho omzimba la ngemva kwamalanga angamatshumi amabili lasitshiyagalombili (28). Ngalesi sikhathi abantu bangakhupha impumela yokuthi kabalagcikwane yona eyabe ingaqondanga. Lanxa abantu abasengozini ye-HIV kumele benze inhlolisiso masinyane. Impumela eziphuma zisithi umuntu kalagcikwane kumele phakathi kwamalanga angamatshumi amabili lasitshiyagalombili ngemva kokuhlangana le-HIV ziyeqinisekiswa ngezinye inhlolisiso kungakadluli inyanga ezintathu.

4. Kumele ngenzeni nxa ngingathola impumela etshengisa ukuthi ngileg cikwane?

Kumele uye kusisebenzi sezempilakahle ukuze uthole okunye ukuhlolisiswa ukuze kuqinisekiswe ngempumela. Ngaleso sikhathi iklinika yesigabeni sakho kanye lalabo abakuncedayo lapho bazethula amanyathela alandelayo okumele athathwe.

Ulwazi oluphathelane lalokho okusetshenziswayo

I-nombolo yokubalula lokho okusetshenziswayo

W006P0058 W006P0059 W006P0060

UKUSETSHENZISWA OKUKHANGELELWEYO

I-Wondfo yinhlolisiso esetshenziswa kanye kuphela ukuzihlola igazi ngokuhlaba umunwe kudingwa i-HIV 1 loba 2. Yenzelwe ukusetshenziswa ukuzihlola kanye loba ukuhlolwa ngabezempilakahle. Yenzelwa ukuhlolela ngaphandle komzimba kuphela.

OKUMELE KWENZIWE KULINHLOLISISO

I-Wondfo HIV Self-Test yindlela yokuthontisela igazi lomuthi oyabe ufakwe kulo kulokho okusetshenziswa ukuhlola igcikwane le-HIV. Nxa igazi lomuthi kungafakwa kokungamagodi okuncane okufaneleyo, kuzazigelezela phakathi kwalokho okokwenza inhlolisiso. Amasotsha omzimba alwisa i-HIV-1 kanye/loba i-HIV-2 ayanamathela kugcikwane le-HIV (gp36/41) njalo imbumba yalokhu iyadonswa yi-HIV (gp41 le gp36) ibisisama lapho okulo-T kulokho okokwenza inhlolisiso.. Nxa ubunengi bamasotsha omzimba alwisa i-HIV-1 loba HIV-2 buphansi bebanga elikhangelelweyo akulamzila olombala ophumayo maqondana lo-T okukhombisa ukuthi impumela ithi i-HIV kayibonakalanga. Ukuqiniseka ukuthi okukhangelelwe ukuthi kwenzeke yikho okwenzakeleyo, umzila olombala uzaphuma maqondana lo-C

IZIXWAYISO LOKULIMUKISA

Ungasebenzisi lokhu okokwenza inhlolisiso nxa ilanga okuthiwa kumele kucine ukusetshenziswa ngalo seledlule.
Ungasebenzisi nxa okuyisiphathelo kudabukile loba kungavalwanga kuhle
Ungasebenzisi ukuzihlola nxa uleminyaka yokuzalwa engaphansi kwelitshumi lambili (12).)
Ungasebenzisi ukuzihlola nxa ulesifo sokopha.
Ungasebenzisi ukuzihlola nxa usuvele wabanjwa ukuthi ulegcikwane le-HIV
Ungavuli okuyisiphathelo andubana usulungele ukwenza inhlolisiso.

Geza izandla zakho njalo uqiniseke ukuthi zihlanzekile njalo zomile andubana uqale inhlolisiso. Kuyadingeka njalo ukuthi kukhanye kuhle ukuze ubale kuhle impumela.

OKUSETSHENZISWAYO UKUQHUBA INHLOLISISO

Kulemihlobo emithathu yalokho okusetshenziswa Ukuhlola. Kulalokho okwenza inhlolisiso eyodwa, kulokunye okwenza ezingamatshumi amabili (20) kube lokwenza inhlolisiso ezilikhulu (100). Okusetshenziswa ukwenza inhlolisiso kuyaqanjwa ngaphansi la:

Okuzingxenye / I-nombolo yokubalula lokho okusetshenziswayo		I-W006P0058	I-W006P0059	I-W006P0060
Isiphathelo sokokwenza inhlolisiso	Okokwenza inhlolisiso (Inani leziqa)	1 (sisodwa)	Owodwa umxhaka ulokokuhlolisisa o kungamatshumi amabili (20)	Owodwa umxhaka Ulokokuhlolisisa okulikhulu (100)
	Okusasawudo lamatshe (Iziqa)	1 (sisodwa)	Owodwa umxhaka ulokokuhlolisisa o kungamatshumi amabili (20)	Owodwa umxhaka Ulokokuhlolisisa okulikhulu (100)
Okunye okokuncedisa ukwenza inhlolisiso	Isiphathelo sokuthontisela igazi	1 (sisodwa)	Owodwa umxhaka ulokokuhlolisisa o kungamatshumi amabili (20)	Owodwa umxhaka Ulokokuhlolisisa okulikhulu (100)
	i-buffer (Isiphathelo somuthi esincane)	1 (iyodwa)	Owodwa umxhaka ulokokuhlolisisa o kungamatshumi amabili (20)	Owodwa umxhaka Ulokokuhlolisisa okulikhulu (100)
	I-IFU (inani)	1 (Iyodwa)	Owodwa umxhaka ulokokuhlolisisa o kungamatshumi amabili (20)	Owodwa umxhaka Ulokokuhlolisisa okulikhulu (100)
	usungulo lokuhlaba olusetshenziswa kanye (inani)	1 (Lulodwa)	Owodwa umxhaka ulokokuhlolisisa o kungamatshumi amabili (20)	Owodwa umxhaka Ulokokuhlolisisa okulikhulu (100)
	Okusabhanditshi okugxanyuzwe kokungamanzi okusatshwala (Inani)	1 (Kukodwa)	Owodwa umxhaka ulokokuhlolisisa o kungamatshumi amabili (20)	Owodwa umxhaka Ulokokuhlolisisa okulikhulu (100)
	Uluthi olulotshinda (inani)	1 (Lulodwa)	Owodwa umxhaka ulokokuhlolisisa o kungamatshumi amabili (20)	Owodwa umxhaka Ulokokuhlolisisa okulikhulu (100)
	Iphepha lokulahlela ingcekeza (inani)	1 (Lilodwa)	/ (Lilodwa)	/ (Lilodwa)

Isiqa sinye ngasinye sephepha lokwenza inhlolisiso singafakwa umuthi silalokhu okulandelayo:I-gold conjugate- (Igcikwane le-HIV elihlangene lomuthi ovusa amasotsha alwisa i-HIV emzimbeni). Umila utshengisa ukuthi ulegcikwane le-HIV kumbe awula (Imithi evusa amasotsha alwisa izifo emzimbeni) lomzila otshengisa ukuthi inhlolisiso ihamba kahle na (imihlobo etshiyeneyo yamasotsha omzimba yomkhakha we-Goat anti rabbit IgG).

UKUGCINWA KWALOKHO OKUSETSHENZISWA KUNHLOLISISO

1. Okokwenza inhlolisiso kungagcinwa okwenyanga ezingamatshumi amabili lane (24) phakathi komumo olezinga lokukhudumala eliphakathi kwe- 2 °C kusiya ku--30 °C
2. Sebenzisa okokwenza inhlolisiso phakathi kwehola elilodwa ngemva kokuvula isiphathelo sakho.
3. Gcinela khatshana lelanga, ubumanzi kanye lesikhudumezi
4. Sebenzisa umxhaka kuzinga lokutshisa eliphakathi kuka-10°C. kusiya ku-30°C.

OKUKHANGELELWE ENHLOLISISWENI

1. Linhlolisiso yenzelwe ukuhlola igazi labantu elithethwe ngokuhlaba umunwe lingahluzwanga
2. Inhlolisiso yenelisa ukubona ukubakhona kumbe ukungabikhona kwamasotsha omzimba alwisa i-HIV-1 kanye le-HIV-2
3. Ingqubo yokwenza inhlolisiso kanye leyokulonda okutshiwo yimpumela kumele kulandelwe kakhulu. Ukuze inhlolisiso isebenze kuhle kakhulu, ukuqoqwa kwesampula ngendlela eqondileyo kuqakathekile. Ukwehluleka ukulandela ingqubo kungakhokhelela empumeleni yenhlolisiso engaqondanga
4. Impumela ephuma isithi akulagcikwane le-HIV lona likhona ingaphuma ngaphansi komumo olandelayo:
   - Izigulane ezihlangane legcikwane le-HIV okwesikhathi esingaphansi kwenyanga ezintathu
   - Izigulane ezelatshwa i-HIV ngama-ARV.
   - Nxa ubunengi bamasotsha omzimba alwisana legcikwane le-HIV asesampuleni bungaphansi bezinga eleneliseka ukubonakala ngendlela yokuhlola le
5. Impumela ephuma isithi kulegcikwane le-HIV lona lingekho ingaphuma ngaphansi komumo olandelayo:
   - Izigulane zike zangena kuchwayisiso lokuzama imithi yokwenqabela i-HIV
6. Ukubakhona komzila oqondane lo-C kutsho kuphela ukuthi okungamanzi okufakiweyo kugelezile, akuqiniseki ukuthi:
   - Kusetshenziswe isampula eqondileyo.
   - Isampula ifakwe ngendlela eqondileyo.
7. Njengayo yonke imihlobo yenhlolisiso yokudinga izifo, inhlolisiso elempumela ethembakeleyo ngempela akumelanga yeyame kumpumela yenhlolisiso eyodwa kodwa kumele yeyame kulokho okubonwa ngowezempilakahle ehlanganisa lempumela yezinye inhlolisiso ezenziwe emalebhu lokunye nje ukuhlolwa. Impumela yenhlolisiso ye-Wondfo esetshenziswa ukuzihlola i-HIV akumelanga isetshenziswe njengendlela eyodwa yokuhlola ukubakhona kumbe ukungabikhona kwesifo.

INDLELA OKWENELISA UKUSEBENZA NGAYO

Echwayisisweni olwenziwayo, abantu abangena kulo abangu-900 ababengazi isimo sabo se-HIV baphiwa inhlolisiso ye-Wondfo yokuzihlola i-HIV. Impumela yaqathaniswa lenhlolisiso zesimanje ezenzelwa emalebhu. Impumela yasemalebhu yakhombisa ukuthi abantu abangu-77 babelegcikwane le-HIV, abangu-822 babengelagcikwane le-HIV kukanti koyedwa akubanga lempumela ecacayo. Abantu abangu-43 (abangu-5 abalegcikwane labangu-37 abangelalo kanye loyedwa olempumela engacacanga) batshiywa phandle ekuhluzweni kokwenelisa ukusebenza kwenhlolisiso. Ukuqathaniseka kwempumela kwaphuma kanje:

- abangu 69 phakathi kwabangu-72) babika kuhle ukuthi impumela yayitshengisa ukubakhona kwegcikwane. Lokhu kutsho ukuthi abantu abathathu abalegcikwane le-HIV babika ukuthi impumela itshengise ukuthi kabalalo igcikwane. Lokhu kubizwa ngokuthi yikungabonakali kwegcikwane okungasiqiniso.
- abangu782 phakathi kwabangu785) babika kihle ukuthi impumela yayitshengisa ukngabikhona kwegcikwane. Lokhu kutsho ukuthi abathathu balabo abangelagcikwane le-HIV babika ukuthi impumela itshengise ukuthi balalo igcikwane. Lokhu kubizwa ngokuthi yoikubonakala kwegcikwane okungasiqiniso
- Isilinganiso se-4.7% sabantu sehluleka ukuthola impumela, isimo somuntu oyedwa owayengene echwayisiweni kasiqinisekanga ngesikhathi sochwayisiso ngakho kasinakwanga ngesikhathi kuchwayisiwa.

UMTHOMBO WOLWAZI

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.

OKUTSHIWO ZIMPAWU

IVD — Okokusebenzisa ukwnza inhlolisiso kwezempilakahle eyenzelwa ngaphandle komzimba	Khangela iziqondiso zokusebenzisa	Ilanga okumele lingadluli kungasetshenziswanga
Ilenani elenele inhlolisiso ezingu-	Ilanga lokwenziwa	Gcina komile
LOT — Uphawu lwenombolo olubalula ukuthi kwenziwe lakuphi okunye	Izinga laphezulu loba elaphansi lokuqanda loba ukutshisa	Kugcine khatshana lelanga
Okwenzileyo)	Ungsebenzisi uphindaphinda	REF — Inombolo ebalula lokho okwenziweyo
Isixwayiso	Angilume uma ikhethiwe iphekhi ilula, funa izishwabekiso zokusebenzisa	

IMININGWANA EPHATHELANE LOKWENZILEYO

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Uyacelwa ukuthi uthinte labo abakwenzileyo loba labo abakuwodisayo endaweni yakini nxa ulemibuzo ephathelena lalokhu okwenziweyo

Tonga

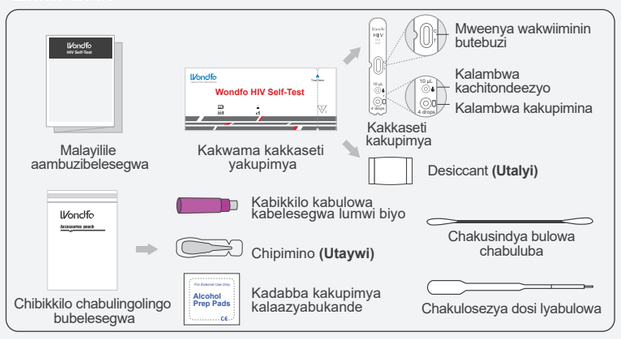
Wondfo Kulipima Nkwelakasasa

Malayilile aambuzibelesegwa

- Kweelede waatobelezya bunonoono malayilile nkukuti ujane butebuzi bunambene.
- Kkala aansi aabusena butakwe tombe, kabiyo aanjila mumuni wazuba kabotu-kabotu. Bona kuti zyoonse zintu nzuyanda kubelesya ulaazyo kutana kutalika kubbibbilika kulipima. Zintu zyakulipimya eezi zibelesegwa lumwi luzutu mpawo wazisowa. Utajuli ka foil pouch kajisi kkasetti yakulipima domane kuli waba muchiimo chakuyanda kulipima.

Yeba vidiyo itondeezya mbukuchitwa

Zilimukati

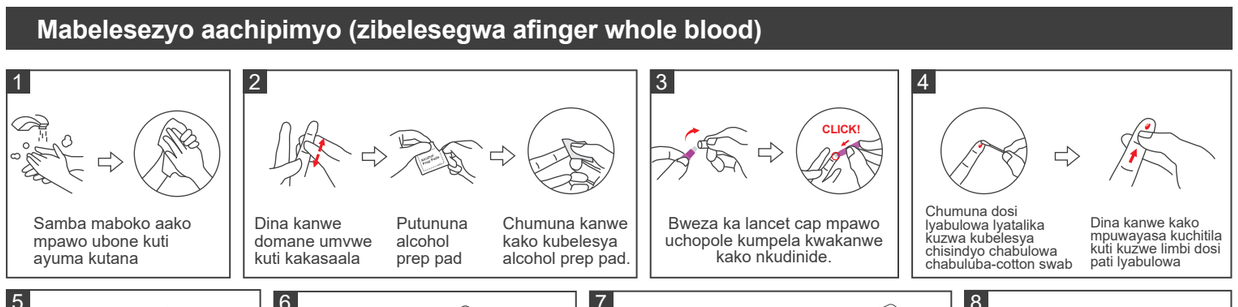


Zintu zikonzya kuyandikana pesi kazili tazipedwe

Chilangya chiindi | Pepa lyatishu | Bbandichi

Kubambila

Mabelesezyo aachipimyo (zibelesegwa afinger whole blood)



Mbububalwa butebuzi bwazwa mukanchina kakulipima

Kwajanika tuzunda twankwelakasasa

Kubawo kwamyeengo yobile yamusyobo usalala aali “T” antoomwe ali “C”

Yinka kukkilinika bakakupime lubo chakufwambaana

Kutajanika kwatuzunda twankwelakasasa

Taakwe keengo kamusyobo uusalala aali “T”

Lipime lubo nikwiinda myeezi iitatu kuti koyeeyela kuti wakali waswaanana awulaankwelakasasa naakuti kuyeeyela kuti ukonzya kujana tuzunda twankwelakasasa nkweendeendela. Buzya zyaatala akulikwabilila kubulwazi bwaNkwelakasasa kukkilinika ilaafwiifwi anduwe.

Teezyazwa kabotu

Kutabawo kwamweengo uusalala aali “C”

Lipime lubo naakuti yinka kukkilinika bakakupime

SOWA

Sowa zyoonse nzuwalikubelesya anzila ili mumulawu wabusena.

Kamwi ka test strip nga kajisi bulingolingo butobela: Gold conjugate (HIV gp41/gp36 fusion recombinant antigen-gold colloid antoomwe arabbit IgG polyclonal antibody-gold colloid), Test line (HIV gp41 recombinant antigen antoomwe aHIV gp36 recombinant antigen) antoomwe aControl line (Goat anti rabbit IgG polyclonal antibody).

MBUKABAMBWA KANCHINA KAKULIPIMA

1. Kanchina kakulipima keelede kabambilwa mubusena bujisi ma temperature alaakati ka 2-30°C kwamyeezi isika kumakumi obile alamyeezi iine (24 months).
2. Belesya test kkaseti mukati ka –awa iimwi kuzwa aawo nuwaputununa.
3. Utakabikki aabusena bunjila zuba, aatete naakuti aapya.
4. Belesya kanchina aaka muma temperature alaakati ka 10-30 °C

BUBI BWAKUBELESYA KANCHINA KAKULIPIMA

1. Chipimo eechi chibelesya kupima bulowa bwagwisigwa kumpela kwakanwe.
2. Chipimo eechi chibelesegwa kukubona bubewo bwa ma antibodies ategwa HIV-1 a HIV-2.
3. Kuti ujane butebuzi bunambene uyelede kutobelezya kabotu malayilile ambukabelesegwa kanchina aaka antoomwe ambubugwisigwa bulowa kuzwa mukanwe kabunjizigwa mukanchina. Kuti teewazitobelezya kabotu eezi, zikonzya kukupa butebuzi bwakubeja.
4. Butebuzi bubeja kuti muntu takwe tuzunda twankwelakasasa bujanika muzyiimo zitobela:
   - Kuti sikupimwa ulaamyeezi ilaansi kwayitatu kali wajatwa bulwazi bwankwelakasasa.
   - Sikupimwa kali muntu uunywa mapilisi a Antiretroviral
   - Kuti kakuli buvule bwama antibodies aali mubulowa alaamweelo utaboneki pe kuti mwaali mudosi lyabulowa lyabikkwa mukanchina.
5. Butebuzi bubeja kuti muntu ulaatuzunda twankwelakasasa bujanika muzyiimo zitobela
   - Sikupimwa wakali wayaswa nsunda yakulikwabilila tuzunda twaHIV iinga ijisi tuzunda twankwelakasasa twakanyeegwa nguzu
6. Bubewo bwamweengo utegwa control line ali (C) chitondeezya kuti dosi lyabulowa lyabikkwa mukanchina lyasaalila mukanchina pesi tazitondeezyi zitobela pe:
   - Kuti buvule bwadosi lyabulowa lyabelesegwa mbubo na
   - Bulowa bwabikkwa mukanchina bwabikkwa munzila ili kabotu na
7. Mbuuli zimwi zipimo zichitwa, kuti muntu ajane butebuzi antoomwe ansandulo imukkutya, uyelede kupimwa twiingi-twiingi kakubelesegwa nzila zisiyenesiyene. Nkaako butebuzi bwazwa mukulipima akanchina ka Wondfo tabweelede kuti bwaba mbubo luzutu bubelesegwa kutondeezya chiimo chamuntu pe chabulwazi bwankwelakasasa.

MBELEKELO YAKANCHINA KAKULIPIMA

Kwakapimwa bantu basika kumyaanda musanu ayine (900) bakatazibinkene pe bwiime bwabo aatala abulwazi bwankwelakasasa. Bantu aaba bakapegwa kanchina ka Wondfo kakulipima kuti balipime kubonwe mbukabeleka kanchina aaka. Butebuzi bwakazwa kukulipima kwabantu aaba basika myaanda musanu ayine bwakatolwa bwaakweezyanisigwa abutebuzi bwakali bwachitwa aayimwi minchina mipati yamuma labbolitali. Butebuzi bwakazwa muminchina mipati yamulabbolitali bwakatondeezya kuti bantu basika kumakumi musanu alaamakumi aabili amusanu atubili (77) bakajanika kabalaatuzunda twankwelakasasa, bantu basika kumyaanda musanu ayitatu ilaamakumi aabili abantu babili (822) bakajanika kabatakwe tuzunda twankwelakasasa, muntu womwe wakajanika katazibikene pe bwiime bwakwe. Bantu basika kumakumi aane abantu batatu (43) bakajanika kabiimvwi boobu – 5 balaatuzunda twankwelakasasa, 37 batakwe tuzunda twankwelakasasa, muntu womwe taakazibikana mpayimvwi nkaambo taakanjila pe muchipimo eechi. Pesi butebuzi nibwakalangisisigwa kwakaboneka kuti:

- 95.8% lyabantu (69/72) bakajanika kabajisi tuzunda twankwelakasasa kuzipimo zyobilwe nzibakachitwa. Eechi chaamba kuti bantu botatwe balaabulwazi bwankwelakasasa bakaboneka kuti tabakwaabo pe. Eezi zitondeezya butebuzi bwakubeja njibati ni false negative.
- 99.6% lyabantu bakapimwa (782/785) bakajanika kabatakwe bulwazi bwankwelakasasa. Eechi chaamba kuti bantu batatu bakapimwa bakatalikwe bulwazi bwankwelakasasa bakajanika kabajisi bulwazi bwankwelakasasa. Eezi zitondeezya butebuzi bwakubeja mbubati ni false positive.
- 4.7% lyabantu (42/900) tebakajana butebuzi pe, bwiime bwamuntu uumwi aatala abulwazi bwankwelakasasa tebwakatondeezegwa pe kuminchina yoonse.

MALEMBE AAKABALWA NIKWAKALEMBWA MALEMBE AAYA

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BWIIME BWAZYIIMININO

IVD — Kanchina kakupimya *in vitro*	Langa malayilile aatala ambuchibelesegwa	Buunsi Bwakusampuka
Zjisi zizulide zya < *n* > chipimyo	Buunsi mbuzyakapangwa	Chibambe kachili chiyumu
LOT — Mweelwe wakupangwa	Mweelo wakupya/ Kutontola wamamanino	Bona kuti tachibikkwi amumuni wazuba
Sikuchipanga	Utabelesyi	REF — Mweelwe wachintu
Nyayilwa zikonzya kukuchisa eezi	Paketi ikali shingi, usankha kumvela kwatendwa kwakwe nokukhumbula masankho aitsa	

Zyaatala asikupanga kanchina aaka

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Wenche jata sikupanga kanchina aaka naakuti ooyo uuwuzya aintu eezi mubusena bwenu kuti kujisi mibuzyo aatala akanchina aaka.