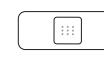
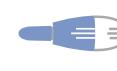




# HIV Self Test

## Instructions For Use

## Contents:



Test Device Pouch

Lancet

STERILE

R

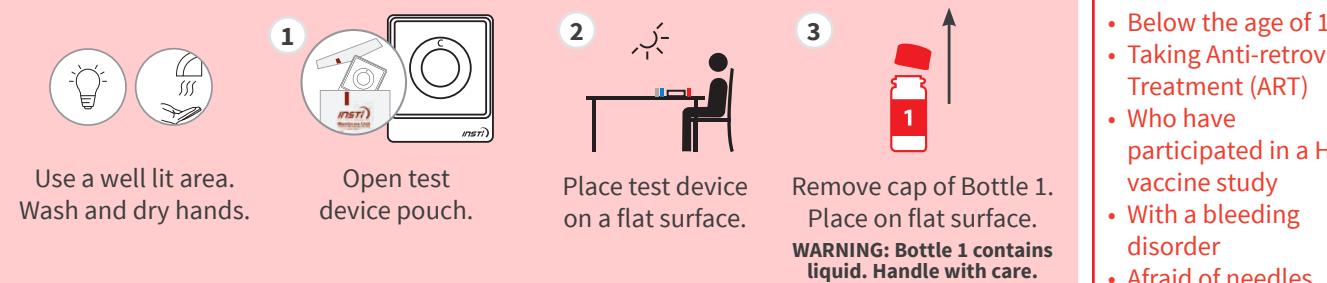
Bandage

## Before You Begin:

- Read instructions carefully before use.
- Do not use if past expiration date on outer packaging.
- Do not use if the test device pouch has been damaged.
- Do not open the pouch until you begin the test.
- Allow test to reach room temperature if stored refrigerated.

Scan to see how the test works. [insti.com](http://insti.com)

## Preparation



## Step 1: Collect Blood

If you have trouble collecting blood, see Questions and Answers section.



## Step 2: Test



## Step 3: Read Result

Read result right away.



Only the control dot appears. Your test result is HIV negative. Result can be incorrect if you engaged in HIV risk activity in the last 3 months. **TEST** again in 3 months.

Two dots mean your test result is positive. You may be HIV positive. Positive results **MUST** be confirmed by a doctor.

**⚠ ONE DOT MAY BE LIGHTER THAN THE OTHER.**

In rare instances, a faint ring may appear at the test dot; this is a positive result.

## Intended Use

The INSTI HIV Self Test is a single use in vitro self-test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in whole blood. The test is intended for use as a self-test by users 18 years or older.

## Disposal

Discard with normal household waste or in accordance with local regulations.

## Warnings and Precautions

- ⚠ Test components are harmful if swallowed due to the presence of Sodium Azide
- All blood samples should be handled as if capable of transmitting infectious diseases.
- Clean up spills.
- Keep out of the reach of children.

## Storage

- 2°C to 30°C Store in the original packaging in a cool, dry location between 2 to 30°C. DO NOT FREEZE.
- Do not store in direct sunlight.
- Do not open the test device pouch until you are ready to take the test.

⚠ Caution. Harmful if swallowed.

⚠ Consult Instructions for Use

⚠ For single use only. Do not reuse.

⚠ Use by

⚠ In vitro diagnostic medical device

⚠ Sterilization using irradiation

⚠ Catalogue Number

⚠ Lot number

⚠ Manufacturer

## Questions and Answers

## General

**1. What is HIV and AIDS?** HIV (Human Immunodeficiency Virus) is the virus that causes AIDS (Acquired Immunodeficiency Syndrome) if left untreated. When a person becomes infected with HIV, the virus begins to attack his or her immune system, which is the body's defense against illness. As a result, that person becomes more susceptible to disease and infection. When his or her body loses the ability to fight diseases, that person is diagnosed with AIDS. There is no cure for HIV infection. However, treatment for HIV is highly effective.

**2. How does someone acquire HIV?** HIV spreads through contact with blood, semen, pre-seminal fluid, rectal fluid, vaginal fluids, or breast milk of an infected person. Transmission can occur from unsafe sex. It can also result from exposure to blood through the sharing of syringes or needles. Women living with HIV can pass the virus to their babies during pregnancy, childbirth, and breastfeeding. HIV is not transmitted by casual contact (sharing food, dishes, clothing, etc.), saliva, casual kissing, food preparation or insect bites.

**3. What is an antibody?** Antibodies are produced by your body's immune system in response to harmful organisms like viruses and bacteria. Their purpose is to defend against infection.

## About the Test

**4. How does the INSTI HIV Self Test work?** INSTI HIV Self Test is a blood test for detecting HIV antibodies. The test produces a result in the form of either one dot (control dot) or two dots (control and test dots). A control dot is the built-in control mechanism and is visible if the test is performed correctly. A test dot will only be visible if sample contains antibodies to HIV. The test is performed by adding a drop of blood to Bottle 1. This diluted sample is then poured into the test device followed by solutions in Bottle 2 and Bottle 3, sequentially after each solution has absorbed through the test device. The test procedure

must be completed in the proper sequence without delays between steps.

**5. How accurate is the test?** Based on a Canadian study on the INSTI HIV-1/HIV-2 Antibody Test, INSTI has a proven:

- » Clinical sensitivity of 99.6%, which means that if 1000 people with HIV antibodies are tested with INSTI, 996 will get a positive test result.
- » Clinical specificity of 99.3%, which means if 1000 people without HIV antibodies are tested with INSTI, 993 will get a negative test result.

In another Canadian study conducted by self-testers, the positive percent agreement was 100%. This means all true HIV antibody subjects were identified as positive by the INSTI HIV Self Test. The negative percent agreement in this study was 99.5%, which means that 614/617 true HIV negative subjects were identified as negative by the INSTI HIV Self Test.

**6. What is a false positive result?** A false positive result is when a test result is positive, but the true HIV status of the person is negative (not infected with HIV).

**7. What is a false negative result?** A false negative result is when a test result is negative, but the true HIV status of the person is positive (infected with HIV).

**8. How early can this test detect HIV?** Based on biolytical's studies, INSTI demonstrates third generation performance and detects HIV antibodies of the IgM and IgG classes. IgM antibodies are the earliest antibodies that the body produces after an HIV infection and can be detectable within 21-22 days<sup>1,2</sup>. Depending on how quickly a person's immune system generates HIV antibodies after exposure, it could still take up to 3 months to get a positive result. If you think you have been exposed to HIV within the last 3 months, and your results are negative, you will need to test again after at least 3 months have passed since your exposure. The time from HIV exposure to when a test can correctly give a positive result is referred to as the 'window period'.

## Test Procedure

**9. How do I make sure I get enough blood?** Before starting the test, relax and drink a glass of water. Warm your hands. Place your hand below waist level to promote blood flow. Before using the lancet, look for a spot on the side of your finger tip that is smooth and not calloused and away from your fingernail.

**10. The contents of Bottle 1, 2 or 3 do not absorb into the test device.** It is very rare for this to happen, but if it does, you will not be able to complete the test procedure and read the results. You will need to perform another test. In some instances, samples may exhibit longer than normal flow times through the test device. This is due to variable factors, such as cellular components within the whole blood sample. Failure to follow the instructions may also result in leakage and/or overflow of liquids from the test device.

**11. What happens if I spill some of the contents of Bottle 1, Bottle 2 or Bottle 3 outside the test device?** Continue with the test procedure. The test result is valid as long as the control dot shows a visible dot after pouring Bottle 3 into the test device.

**12. How will I know if my test was done correctly?** The INSTI HIV Self Test has a built-in control dot to show that the test has been performed correctly and that you have added the proper sample type and amount of blood sample. If the control dot does not appear (invalid test result), your test has not worked. It is not possible to draw conclusions from this result and you will need to perform another test. In the event of repeated invalid results, consult a doctor.

## Test Results

If you are unsure of your result you should go to a doctor to perform more testing.

**13. When can I read the result?** You can read the result instantly or within 1 hour of completing the test procedure. Make sure the control dot is present before reading your result.

**14. I have used the test but no dots appeared. What should I do?** Make sure you have adequate lighting. If no dots are visible, you may not have completed the test correctly, or collected enough blood. You will need to perform another test.

**15. What do I do if the result is positive?** A **Positive Result**: Consult a doctor as soon as possible and inform him/her that you have performed a self test for HIV. All positive results must be confirmed by a laboratory test. HIV is preventable and you must avoid high risk sexual behaviors to prevent passing HIV to your partner.

**16. What's Next After A Positive Result?** Having HIV does not mean you have AIDS. With early diagnosis and treatment, it is unlikely that you will develop AIDS. Discuss the next steps with your doctor or counsellor.

**17. What do I do if the result is negative?** A **Negative Result**: As with many tests, there is a chance for false results. If you have a negative result but you were involved in an HIV-risk activity in the past 3 months, you could be in what is called the "window period" and it is recommended to repeat testing at a later date.

**18. Can any medication or medical conditions affect the result?** A false negative result can occur if:

- » You have been on long term anti-retroviral treatment.
- » You have a severe blood disorder, such as multiple myeloma.
- » You have higher than normal haemoglobin.

There are no other known interferences. It is recommended to read the manufacturers' instructions for other medications you are taking before conducting the test.

Manufactured by:  
biolytical Laboratories, Inc.  
406-13251 Delf Place  
Richmond, BC, Canada V6V 2A2  
Phone: +1 604-204-6784  
[www.biolytical.com](http://www.biolytical.com)

90-1044, 90-1053 INSTI HIV Self Test  
51-1220C 26-Oct-2020

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## For Questions Or Further Support Call your provincial and territorial HIV/AIDS hotlines:

AB: 811 or 1-800-772-2437  
BC: 811 or 1 800 661-4337  
SK: 811 or 1 800-667-6876  
NL: 1-800-563-1575  
NB: 1-800-561-4009  
NT: 1-800-661-0844

NU: 1-800-661-0795  
NS: 1-800-566-2437  
PE: 1-800-314-2437  
QC Info-Santé: 811  
Portail VIH/sida du QC:  
1-877-Portail (767-8245)

YT: 1-800-661-0408 ext.8323  
EASTERN ARCTIC:  
1-800-661-0795  
MB: 211, Health Links at 204-788-8200, toll-free 1-888-315-9257 or  
1-800-782-2437

ON: 1-800-668-2437 (EN),  
1-800-267-7432 (FR)  
ON e-chat: [sexualhealthontario.ca/en/chat](http://sexualhealthontario.ca/en/chat)



# Autotest VIH

## Mode d'emploi

## Contenu:



Pochette du dispositif de test

Lancette STERILE

Pansement

Bouteilles 1, 2, 3

## Préparation



Utilisez dans un endroit bien éclairé. Lavez et séchez vos mains.

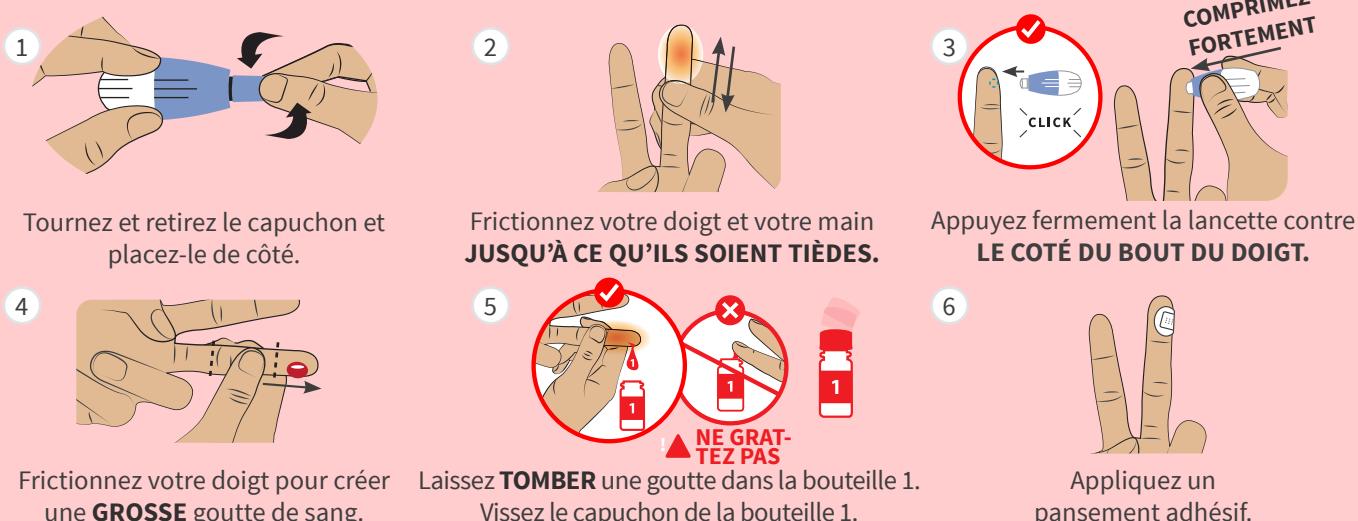


## Ne convient pas aux utilisateurs :

- De moins de 18 ans
- Suivant un traitement antirétroviral (TAR)
- Ayant participé à une étude portant sur un vaccin contre le VIH
- Présentant un trouble de coagulation
- Ayant peur des aiguilles

## Étape 1 : Prélever du sang

Si vous avez de la difficulté à prélever du sang, consultez la section Questions et réponses.



## Étape 2 : Test



## Étape 3 : Lecture du résultat

Lisez le résultat immédiatement.



Seul le point de contrôle apparaît. Le résultat de votre test de VIH est négatif. Le résultat peut être inexact si vous êtes impliqué(e) dans une activité à risque élevé de contracter le VIH au cours des trois derniers mois. **REFAITES UN TEST** dans trois mois.

La présence de deux points signifie que le résultat de votre test est positif. Vous êtes probablement séropositif (séropositif). Les résultats positifs DOIVENT être confirmés par un médecin.

**Un point pourrait être plus pâle que l'autre.**

Dans de rares cas, un anneau flou peut apparaître sur le point de test; c'est un résultat positif.

## Usage prévu

L'Autotest VIH INSTI est un test immunologique in vitro pour la détection d'anticorps contre les virus de l'immunodéficience humaine de type 1 (VIH-1) et de type 2 (VIH-2) dans le sang total. Le test est destiné à être utilisé comme un autotest par des personnes de 18 ans et plus.

## Élimination

Jeter avec les déchets ménagers ou en respectant la réglementation locale.

## Mises en garde et précautions

- ⚠ Les composants du test sont nocifs en cas d'ingestion en raison de la présence d'azide de sodium.
- Tous les échantillons de sang doivent être manipulés comme s'ils étaient susceptibles d'entraîner la transmission de maladies infectieuses.
- Nettoyer les déversements.
- Garder le test hors de portée des enfants.

## Entreposage

- 2 °C à 30 °C Entreposer dans l'emballage d'origine dans un endroit frais et sec entre 2 et 30 °C. NE PAS CONGÉLER.
- Ne pas entreposer à la lumière directe du soleil.
- Ne pas ouvrir la pochette du dispositif de test avant d'être prêt(e) à effectuer le test.

⚠ Mise en garde. Nocif en cas d'ingestion.

⚠ Consulter le mode d'emploi

⚠ À usage unique. Ne pas réutiliser.

⚠ Utiliser avant

⚠ Dispositif médical de diagnostic in vitro

⚠ Stérilisation par irradiation

⚠ Numéro de catalogue

⚠ Numéro de lot

⚠ Fabricant

Vous pouvez lire le résultat du test

immédiatement ou dans l'heure

qui suit la fin de la procédure du

test. Assurez-vous que le point

témoin est présent avant de lire

vos résultats.

14. **J'ai utilisé le test, mais aucun point n'est apparu. Que dois-je faire?** Assurez-vous d'avoir un éclairage adéquat. Si aucun point n'est visible, vous n'avez peut-être pas effectué le test correctement ou vous n'avez peut-être pas recueilli suffisamment de sang. Vous devrez effectuer un autre test.

15. **Que dois-je faire si le résultat est positif?** Un **Résultat positif**: Consultez un médecin dès que possible et informez-le que vous avez effectué un autotest pour le VIH. Tous les résultats positifs doivent être confirmés par un test de laboratoire. Le VIH est évitable et vous devez éviter les comportements sexuels à haut risque afin d'éviter de transmettre le VIH à votre partenaire.

16. **Qu'arrive-t-il après un résultat positif?** Être infecté(e) par le VIH ne signifie pas que vous avez le SIDA. Il est peu probable que vous développiez le SIDA avec un diagnostic et un traitement précoce. Discutez des prochaines étapes avec votre médecin ou conseiller.

17. **Que dois-je faire si le résultat est négatif?** Un **Résultat négatif**: Comme avec beaucoup de tests, il est possible que le résultat soit erroné. Si vous obtenez un résultat négatif, mais que vous avez été impliqué(e) dans une activité à risque élevé de contracter le VIH au cours des trois derniers mois, vous pourriez être, dans ce qu'on appelle la « fenêtre sérologique » et il est recommandé de répéter le test à une date ultérieure.

18. **Le résultat du test peut-il être affecté par certains médicaments ou certaines maladies?** Un faux résultat négatif peut se produire si:

- » Vous avez suivi un traitement antirétroviral à long terme.
- » Vous êtes atteint(e) d'un trouble sanguin grave, comme un myélome multiple.
- » Vous présentez un taux d'hémoglobine supérieur à la normale.

Il n'y a pas d'autres interférences connues. Il est recommandé de lire les instructions du fabricant pour les autres médicaments que vous prenez avant de procéder au test.

## Si vous avez des questions ou besoin d'un soutien supplémentaire

Appelez la ligne directe pour le VIH/SIDA de votre province ou de votre territoire :

**AB**: 811 or 1-800-772-2437  
**CB**: 811 or 1 800 661-4337  
**SK**: 811 or 1 800-667-6876  
**NL**: 1 800 563-1575  
**NB**: 1 800-561-4009  
**NT**: 1 800-661-0844

**NU**: 1 800-661-0408 poste 8323  
**YT**: 1 800-661-0795  
**NS**: 1 800-566-2437  
**PE**: 1 800-314-2437  
**QC Info-Santé**: 811  
**Portail VIH/sida du QC**: 1-877-Portail (767-8245)

**ON**: 1 800-668-2437 (EN),  
1 800-267-7432 (FR)  
**ON e-chat**: sexualhealthontario.ca/en/chat  
**MB**: 211, Health Links at 204-788-8200, toll-free 1-888-315-9257 or  
1-800-782-2437

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