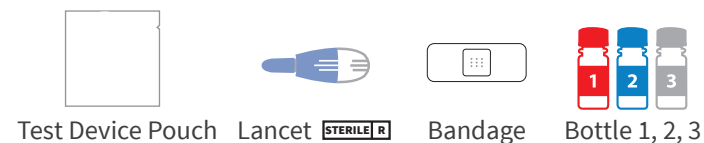




HIV Self Test

Instructions For Use

Contents:



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](https://www.insti.com)

Preparation

- Use a well lit area. Wash and dry hands.
- Place test device on a flat surface.
- Remove cap of Bottle 1. Place on flat surface. **WARNING: Bottle 1 contains liquid. Handle with care.**

Not for users:

- Below the age of 18
- Taking Anti-retroviral Treatment (ART)
- Who have participated in a HIV vaccine study
- With a bleeding disorder
- Afraid of needles

Step 1: Collect Blood

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

- Twist and pull off tip and put aside.
- Rub finger and hand **UNTIL WARM**.
- Press the lancet hard against the **SIDE OF FINGER TIP**. **PRESS HARD**
- Rub finger to create a **LARGE** drop of blood.
- Let **1 drop FALL** into Bottle 1. **DO NOT SCRAPE**. Twist on cap of Bottle 1.
- Apply adhesive bandage.

Step 2: Test

- SHAKE 4 TIMES** **POUR ALL**. Shake and pour all liquid. Wait until liquid disappears.
- SHAKE 4 TIMES** **POUR ALL**. Shake and pour all liquid. Wait until liquid disappears. **TIP: Gently tap Bottle 2 to pour liquid.**
- SHAKE 4 TIMES** **POUR ALL**. Shake and pour all liquid. Wait until liquid disappears.

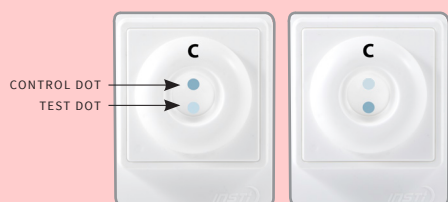
Step 3: Read Result

Read result right away.



Negative

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.



Positive

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.



Invalid

The control dot did not appear. Your test did not work. Control dot must appear to indicate that the test has been performed correctly. **REPEAT** the test with a new test kit.

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.

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

- 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

Disposal

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

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^{1,2}. 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'.

¹Moshgabadi N, et al. "Sensitivity of a rapid point of care assay for early HIV antibody detection is enhanced by its ability to detect HIV gp41 IgM antibodies." J Clin Virol (2015) Oct; 71:67-72.
²Cohen M, et al. "The detection of acute HIV infection" J.Infect. Dis. 202 (2010) 270-277.

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.

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

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|----------------------------------|---|--|---|
| AB: 811 or 1-800-772-2437 | NU: 1-800-661-0795 | YT: 1-800-661-0408 ext.8323 | ON: 1-800-668-2437 (EN), 1-800-267-7432 (FR) |
| BC: 811 or 1 800 661-4337 | NS: 1-800-566-2437 | EASTERN ARCTIC: 1-800-661-0795 | ON e-chat: sexualhealthontario.ca/en/chat |
| SK: 811 or 1 800-667-6876 | PE: 1-800-314- 2437 | MB: 211, Health Links at 204-788-8200, toll-free 1-888-315-9257 or 1-800-782-2437 | |
| NL: 1-800-563-1575 | QC Info-Santé: 811 | | |
| NB: 1-800-561-4009 | Portail VIH/sida du QC: 1-877-Portail (767-8245) | | |
| NT: 1-800-661-0844 | | | |

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