



# HIV Self Test

Instructions for Use

## Contents



## 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

## Before You Begin

- Read instructions carefully before use.
- Do not use if past expiration date on outer packaging.
- Do not use if the test pouch has been damaged or if any of the components are missing.
- 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.

## Preparation



Use a well lit area. Wash and dry hands.



Place membrane unit on a flat surface.



Open membrane unit pouch.

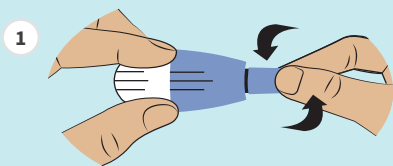


Remove cap of Bottle 1. Place on flat surface.

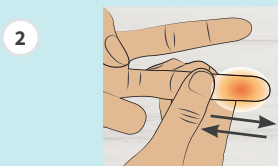
**WARNING: Bottle 1 contains liquid. Handle with care.**

## Step 1: Collect Blood

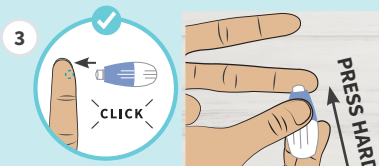
If you have trouble collecting blood, see Questions and Answers section or Scan the QR code to watch the training video.



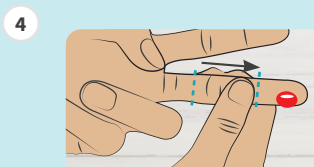
Twist and pull the blue tip out of the lancet and place aside.



Rub finger **UNTIL WARM.**



Secure finger firmly on hard surface and press lancet on the **side** of the fingertip.



Rub finger to create a **LARGE** drop of blood.

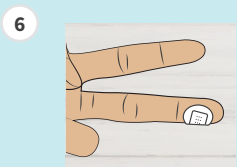
**ENSURE THAT A FULL, PEA-SIZE DROP OF BLOOD IS PRODUCED (SEE STEP 5) TO AVOID AN INVALID RESULT.**



Let **1 full (a pea-size) drop** fall into Bottle 1. Twist on cap of Bottle 1.

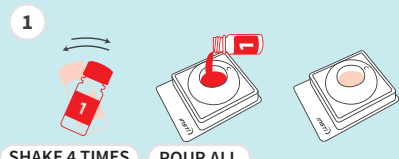


**DO NOT DRIBBLE, SCRAPE AND/OR SPILL. STOP THE TEST IMMEDIATELY IF BLOOD IS ADDED TO BOTTLE 2.**



Apply adhesive bandage.

## Step 2: Test



**SHAKE 4 TIMES POUR ALL**

Shake and pour all liquid. Wait until liquid disappears.

**IMMEDIATELY POUR THE SAMPLE ON THE MEMBRANE AFTER ADDING BLOOD TO BOTTLE 1 AND SHAKING. DELAYS LONGER THAN 10 MINUTES COULD RESULT IN A FALSE POSITIVE RESULT.**



**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.

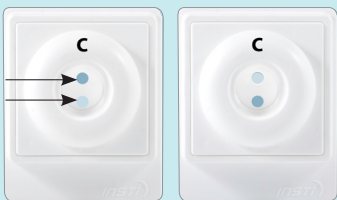
## Step 3: Read Result

Read result right away to **within 1 hour.**



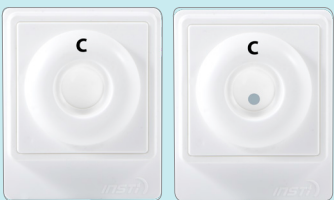
**Negative**

Your test result is HIV negative. 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**

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, rapid, in vitro diagnostic qualitative immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and/or Type 2 (HIV-2) in human fingerstick whole blood. This test is intended for over-the-counter (OTC) consumer use as an aid in the diagnosis of infection with HIV-1 and HIV-2. The test is intended for use as a self test by users 18 years or older. It is not intended to be used with specimens other than fingerstick whole blood.

## 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.

## Questions and Answers

### General

**1| What are 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. To learn more, call your national HIV/AIDS hotline: **CDC National AIDS Hotline; 1-800-CDC-INFO (1-800-232-4636); TTY: 1-888-232-6348 (24/7) English and Spanish**

**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 result in the form of either one dot (control dot) or two dots (control and test dots). 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 membrane unit followed by solutions in Bottle 2 and Bottle 3, sequentially after each solution has absorbed through the membrane unit. Test procedure must be completed in the proper sequence without delays between steps.

**Note:** Do not continue the test if Bottle 1 is poured into Bottle 2 instead of membrane unit or if blood is dropped into Bottle 2 instead of Bottle 1.

**5| How accurate is the test?** Performance of the test: In a clinical study, 1,587 individuals who were unaware of their HIV status tested themselves for HIV using the INSTI HIV Self Test, and their results were compared with the results from a test performed by a trained professional. Twenty-three individuals had positive results and 1,521 had negative results on the self test. There were no differences between the self test and the professional test results, which means that there were no false positive or false negative results. Forty-two (2.7%) individuals using the self test failed to obtain a valid result. One individual was unable to complete the 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 human HIV-1 IgM antibodies. IgM antibodies are the earliest antibodies that the body produces after an HIV-1 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'.

<sup>1</sup>Moshgabadi 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.  
<sup>2</sup>Cohen M, et al. " The detection of acute HIV infection" J.Infect. Dis. 202 (2010) 270-277.

## For any Questions/Concerns call

**bioLytical Laboratories Technical Support/Customer Service:**  
**1-866-674-6784 x 200 or customercare@biolytical.com**  
**Hours of Operation: 8:00 AM to 8:00 PM PST, 7 days a week (English Only)**

## 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 membrane unit pouch until you are ready to take the test.

## Explanation of Symbols

- Caution. Harmful if swallowed.
- Consult Instruction for Use
- For single use only. Do not reuse.
- Use by
- In Vitro diagnostic medical device
- Sterilization using irradiation
- Catalogue Number
- Lot number
- Manufacturer
- Do not use if damaged

## 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 membrane unit.** 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 membrane unit. 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 membrane unit.

**11| What happens if I spill some of the contents of Bottle 1, Bottle 2 or Bottle 3 outside the membrane unit?** 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 membrane unit.

**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.

This test is approved by FDA for use with fingerstick whole blood specimens only. Use of other types of specimens may not yield accurate results.

## 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 can help to stop the spread of HIV. It is highly recommended to 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 in 3 months.

**18| What do i do if the result is Invalid?** An **Invalid Result** means your test did not work. Control dot must appear to indicate that the test has been performed correctly. Even if the test dot is present but no control dot, the result is considered Invalid. **REPEAT** the test with a new test kit.

## 19| Can any medication or medical conditions affect the result?

- Always read the manufacturers' instructions for any medication you are taking before conducting the test.
- A false negative result can occur for the following reasons:
  - > Have been on long term anti-retroviral treatment
  - > Have a severe blood disorder, such as multiple myeloma
  - > Have higher than normal hemoglobin
  - > If you are using pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) treatment

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