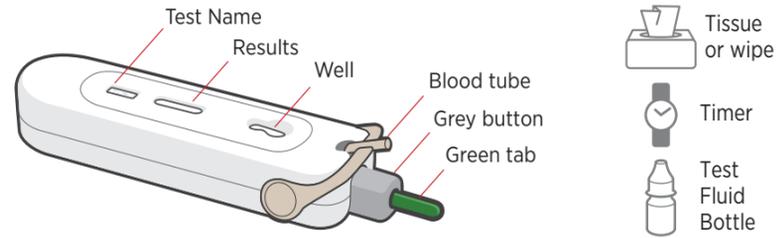


Watch the video: [www.atomohivtest.com](http://www.atomohivtest.com)

You need these four items:

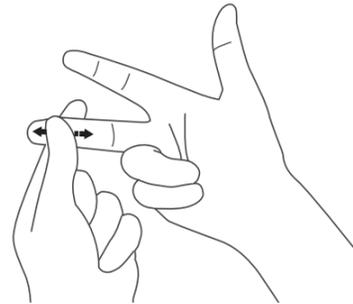


EN Need more help? Turn over page.

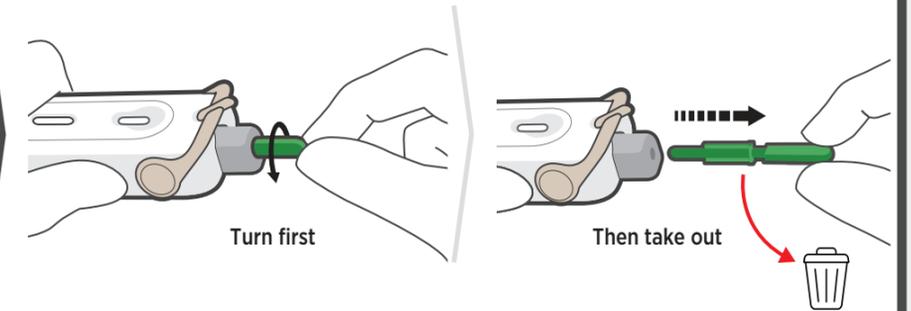
**1** Wash and dry hands. Check expiry date before you open the foil pouch.



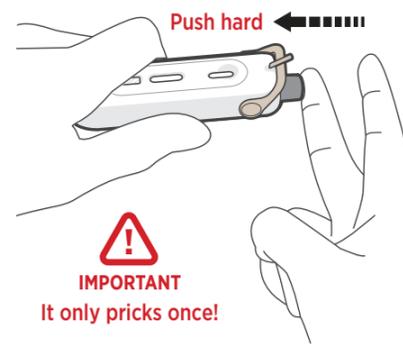
**2** Massage your finger for 5 to 10 seconds.



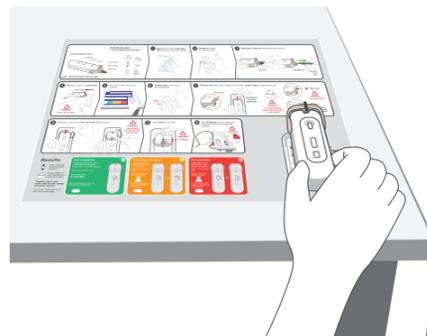
**3** Gently turn and take out the green tab, then discard it.



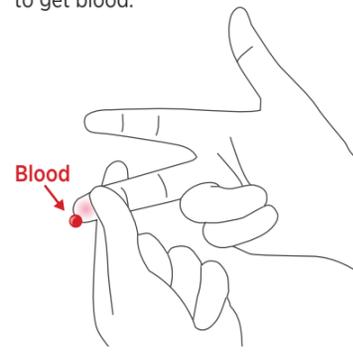
**4** Push grey button in to prick finger.



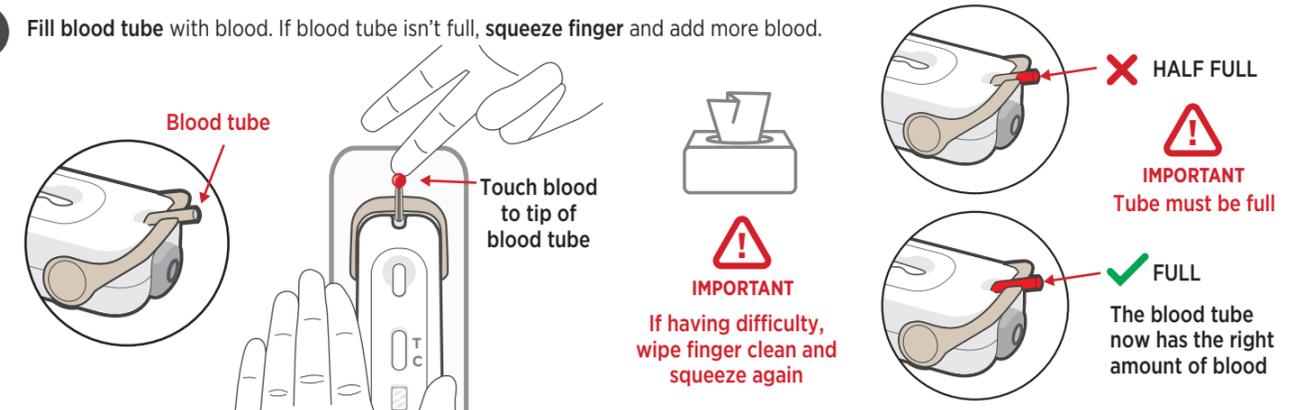
**5** Place test on instructions next to results.



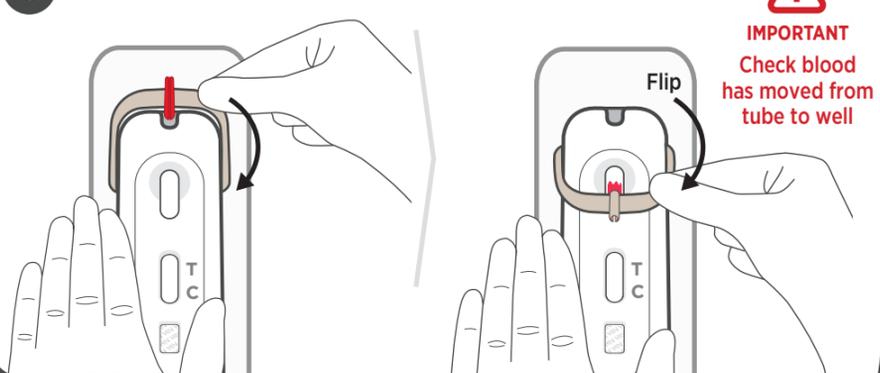
**6** Squeeze firmly behind prick site to get blood.



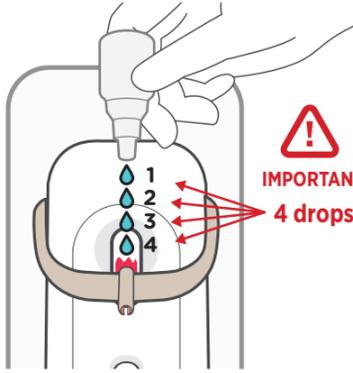
**7** Fill blood tube with blood. If blood tube isn't full, squeeze finger and add more blood.



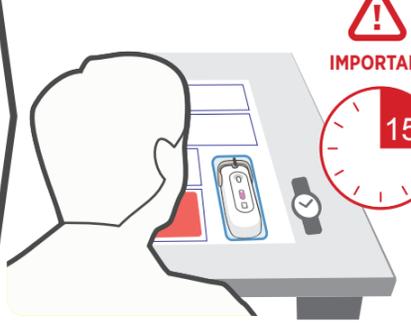
**8** Hold test on table. Now flip blood tube over to the well.



**9** Add 4 drops in the well.



**10** Wait 15 minutes before reading the result. Do not wait more than 20 minutes.



## Results

Make sure you wait the full 15 minutes.

If your finger is still bleeding use a tissue or wipe.

Carefully match your result with the red, orange and green options.

For more information on HIV, turn over page.

### HIV negative

If **one line** appears at the C, you tested HIV negative. There must be no line at the T.

This is a screening test.

Test again after **3 months**.

See included care card for additional information.



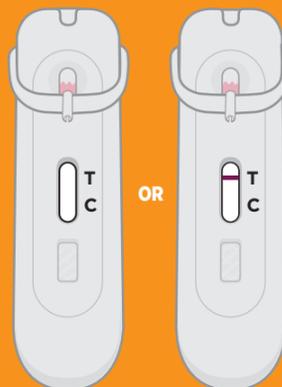
### Test did not work

If **no line** appears at the C, the test did not work.

This is a screening test. Go to a clinic for further testing.



See included care card for additional information.



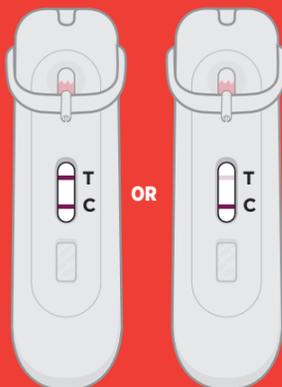
### HIV positive

If **two lines** appear, even if faint, you tested HIV positive.

This is a screening test. Go to a clinic for further testing.



See included care card for additional information.



**IMPORTANT**  
Leave test here, this helps with filling the blood tube



# Need Help with the Test?

## Finger Prick

### Having trouble removing the green tab?

- First turn the tab 90°, then pull it out.

### Scared it will hurt?

- Don't worry, it feels like a rubber band snap against your finger.
- You will not see the needle.

### Pushed the grey button but can't see blood?



Is the button out?  
Try again, push hard.



Is the button in?  
Squeeze your finger firmly, if you still don't have blood - stop, and get a new test.

Note: It only pricks once!

## Filling the Blood Tube

### Don't know where to put the blood?

- The blood tube is straw coloured, turn page over to see diagram in step 7.
- Do not put the blood in the grey button hole.
- Do not put the blood directly in the well.
- Fill the blood tube, it measures the correct amount of blood.
- Skin touching the tube won't affect the result.

### Can't fill the blood tube?

- If blood smears, wipe your finger, then squeeze your finger firmly again.
- Point your finger down.
- Gently touch blood to the tip of the tube.

- If you don't have enough blood, wipe your finger, then squeeze your finger firmly again.
- If you still don't have enough blood to fill the tube completely, the test result won't be accurate. Stop, and get a new test.

## Completing the Test

### What if the blood does not move from the tube to the well?

- Make sure the tube is full.
- Make sure the tube is completely flipped over to the well.
- If the blood still won't move to the well - stop, and get a new test.

### Not sure how to add 4 drops from the bottle?

- The 4 drops must go into the well on top of the blood.
- Don't shake the bottle.
- Point the bottle down, then squeeze.

### Not sure how to read the result?

- Make sure you wait 15 minutes. Don't wait longer than 20 minutes.
- It is the lines next to the "T" and "C" that tell you your result.
- Turn page over and find the coloured box that matches your result.
- For more information about the result, read the next section: "About Your Result".

Refer to the **Care Card** included in the box for additional information and contact details for local support services.

# About Your Result

There are two types of Human Immunodeficiency Virus (HIV) called HIV-1 and HIV-2. If you are infected with either HIV-1 or HIV-2, your immune system will generate antibodies against either virus type. Atomo HIV Self Test is designed to detect these antibodies to determine if you are infected with either of the two virus types. The test can detect these antibodies in a human blood sample and the test can only be used once.

The test provides results in 15 minutes. If a positive result is detected, it must be confirmed using an alternate test performed by a health care professional, as this is a screening test only.

## What is the "window period"?

It can take 6 to 12 weeks after being exposed to HIV before your body develops the antibodies that are used by this test to detect if you have HIV. This time is called the "window period". If you take an HIV self test during the "window period" (in the first 3 months after being exposed to HIV), before your body has developed antibodies you may falsely test negative. If you believe you have been exposed to HIV, it is recommended to test again after the window period has passed and speak to a healthcare professional particularly if the negative result was not what you expected.

## What happens if my test result is NEGATIVE?

First, it is important to know whether it has been over 3 months since your last risk event. If it has been over three months, and you used the test correctly, then you are likely to be HIV negative. If it has been less than 3 months since a risk event, you will need to repeat the test in 3 months. Remember this is a screening test, if you are unsure, seek advice, refer to the **Care Card**.

**Important: Retest after 3 months.**

## What happens if my test result is POSITIVE?

Being HIV positive is a manageable condition and people living with HIV are now able to live long, active and healthy lives. An Atomo HIV Self Test is a screening test only, and getting a positive test result does not confirm that you have HIV.

If the test result is positive, you need to go for a follow up test at your closest health facility. The earlier a diagnosis is confirmed, the earlier you can start treatment if it is confirmed you have HIV. Refer to the **Care Card** included in the box or visit [www.atomotest.com](http://www.atomotest.com) for more information about how to get a follow up test.

Only your doctor or a healthcare professional can perform further evaluation and recommend what treatment is right for you. If you are diagnosed by a healthcare professional as HIV positive, you will be connected to counselling services and, dependent on your condition, may be put onto antiretroviral (ARV) treatment.

## What happens if my test doesn't work?

It means that the test was not performed correctly or something went wrong. You will need to repeat the test again with a new test device.

If you are unsure whether you've done the test correctly, go to your local clinic or healthcare professional for assistance.

## I am worried I have been exposed to HIV in the last few days, what should I do?

You should visit your local HIV clinic or Accident and Emergency (A&E) department as soon as possible, no longer than 72 hours, as you may be able to access a course of medication called "PEP" (Post-Exposure Prophylaxis) to prevent you from becoming HIV positive (may not be available in all states or countries).

# About HIV

## What is HIV?

"HIV" stands for Human Immunodeficiency Virus. It is a virus that targets the immune system and over time reduces the body's ability to fight infection. HIV reproduces in the body and if left untreated, weakens the immune system and can lead to the body developing Acquired Immune Deficiency Syndrome (AIDS). Although there is no cure for AIDS or HIV, with the correct medical treatment and medication it can be managed as a chronic, but not life threatening, condition. Life expectancy for someone diagnosed with HIV today is similar to someone who does not have HIV, if they start treatment as soon as possible and remain on regular treatment.

## What are the signs and symptoms of HIV?

The only way to know if you have HIV is to have an HIV test. It is very important to get tested to prevent passing on the virus to others without knowing.

## How is HIV acquired or passed on?

HIV is present in bodily fluids such as blood, breast milk, semen, anal mucous and vaginal fluids. Person to person transmission of HIV occurs when there is direct blood to blood contact with another person's blood, semen, anal mucous or vaginal fluids who has HIV. The risk of passing on and acquiring HIV is increased in the presence of an untreated sexually transmitted infection (STI); e.g. chlamydia, gonorrhoea, syphilis and blood borne viruses such as hepatitis C. HIV can also be transferred to a newborn baby from an HIV positive mother during childbirth and while breastfeeding particularly in areas where prenatal screening for HIV is not offered.

## What are Risk Events?

A "risk event" is an activity which may heighten your chance of exposure to HIV, such as:

- Unprotected sex with someone who has HIV or whose HIV status is unknown.
- Unprotected sex (vaginal or anal intercourse) with a number of partners.
- Using unsterile needles or injecting equipment.

## HIV is NOT transmitted by:

- Casual contact (shaking hands, sharing a cup or clothing, etc).
- Kissing.
- Saliva or spitting.
- Tears.
- Sweat.
- Air or water.

## HIV infection can be prevented by:

- Wearing a condom during vaginal or anal sex.
- Talking to sexual partners about their testing history and their current HIV test status.
- Encouraging sexual partners to get tested.
- Using sterile needles or syringes.
- Using Pre Exposure Prophylaxis (PrEP), a medication used to treat HIV positive people, taken by HIV negative people to reduce the risk of acquiring HIV (may not be available in all states or countries).
- Using Post Exposure Prophylaxis (PEP), a course of HIV medication which, if started within 72 hours after a risk event, is believed to significantly reduce the chances of becoming infected (may not be available in all states or countries).



Visit [www.atomohivtest.com](http://www.atomohivtest.com) to watch an instructional video. If you have any specific questions email [support@atomohivtest.com](mailto:support@atomohivtest.com)

**atomo**

## Summary of the Test

The Atomo HIV Self Test is comprised of a paper test strip inside a plastic cartridge. The test is performed by placing a small drop of blood on the test strip and then applying drops of test fluid (diluent). When the test is completed, two lines can appear on the paper strip. The Control Line will only become visible if the test has been performed correctly. The Test Line will only become visible if the applied sample contains antibodies to HIV.

## Intended Use

The Atomo HIV Self Test is a single-use, immunochromatographic, rapid in-vitro diagnostic test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in whole blood. The Atomo HIV Self Test is intended to be used by untrained lay users as a self test to aid in the diagnosis of infection with HIV-1 and HIV-2 from samples of fresh, whole blood obtained through a finger stick blood collection technique. The device requires a sample size of 10uL. The test result is qualitative ("your test is positive" or "your test is negative") and not for screening blood donors.

The test incorporates an in-built sample control mechanism to ensure that the test has been performed correctly; this control line only appears on the test device if the correct test procedure has been followed.

## Materials Included

- 1 - Instructions for Use (IFU)
- 1 - Atomo HIV Self Test (in foil packet with desiccant)
- 1 - Bottle of Test Fluid (Diluent)
- 1 - Disposal bag
- 1 - Care Card

## Items NOT included but required

- Box of tissues (or other clean, absorbent material).
- Timer (for example a watch, clock or mobile phone) to track time while waiting for results.

## Restrictions on use

- Not suitable for screening blood donors.

- Not suitable for people with bleeding disorders (e.g. haemophilia).
- Not suitable for people with a fear of needles.
- Not suitable for people already diagnosed as HIV positive.
- Not suitable for people taking anti-retro viral treatment (ART).

## Limitations of the Test

- May not detect HIV infections that have occurred within the last 3 months.
- The procedure, precautions and interpretation of results must be followed when using this test.
- Only indicates the presence of antibodies to HIV. Not to be used as the sole criteria for the diagnosis of HIV infection or treatment.
- Positive results must be confirmed by a healthcare professional.
- The user should not take any decision of medical relevance with regard to their condition without first consulting a healthcare professional.
- A negative result does not at any time preclude the possibility of HIV infection. If the test result is negative and clinical symptoms are present, additional testing using other clinical methods is recommended.

## Warnings and Precautions

- The test is single use only. Do not re-use the test.
- All positive test results must be confirmed through testing by a health care professional.
- Do not use if the expiry date has elapsed.
- Do not use if the foil packet is damaged (e.g. torn, hole or the seal is broken) or open.
- Do not use if sterility tab is damaged or loose
- Do not use any other solution besides the test fluid that was packed with the test.
- Do not use a test fluid bottle that has been opened or is leaking.
- Avoid eye/skin contact with the test fluid.
- If the test fluid is added to the test strip without any blood, the test is invalid even if the control band appears.
- If instructions are not followed properly, results could be false.

## Disposal

To dispose of the Atomo HIV Self Test, place the test and all box contents into the disposal bag provided. The bag can then be sealed and thrown away with household rubbish.

## Storage

- The test must be stored between 2°C to 30°C.
- Do not store in direct sunlight.
- Do not open the foil packet until you are ready to take the test. Bring the pouch to room temperature, then use immediately upon opening.

 IN VITRO DIAGNOSTIC MEDICAL DEVICE	 CAUTION	 STORAGE TEMPERATURE 2°C - 30°C
 DO NOT USE IF PACKAGE IS DAMAGED	 DO NOT REUSE	 CONSULT INSTRUCTION FOR USE

## Test Performance

### Laboratory Evaluation

- In a 1000-sample study performed by the German Red Cross (Baden-Wuerttemberg-Hessen, Germany), the determined specificity was 100.0%.
- In a 320-sample study performed by the Institute of tropical Medicine (Antwerp, Belgium), the determined sensitivity was 99.6% for HIV-1 and 100.0% for HIV-2.

### In-Field Evaluation

- In a 203-patient study performed by the Kenya Medical Research Institute (Nairobi, Kenya), the determined specificity and sensitivity (accuracy) was 100.0%.

### Manufacturer

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