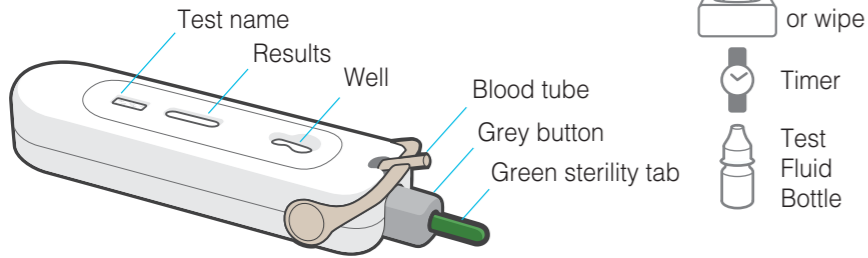


Watch the video: <http://www.mylan.in/en/mylanhivselftest>

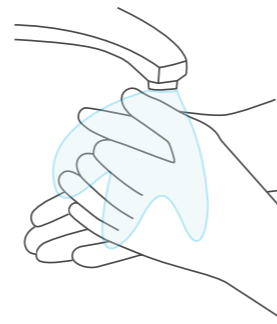
You need these four items:



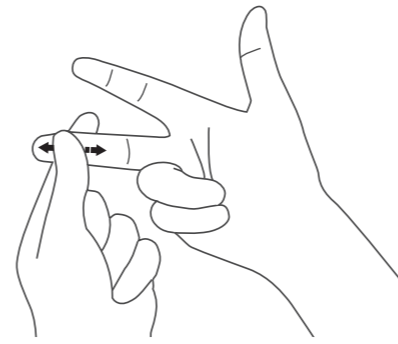
IMPORTANT: Do not open the foil package until you have read the instructions and are ready to take the test. Use immediately upon opening.

EN Need more help? Turn over page.

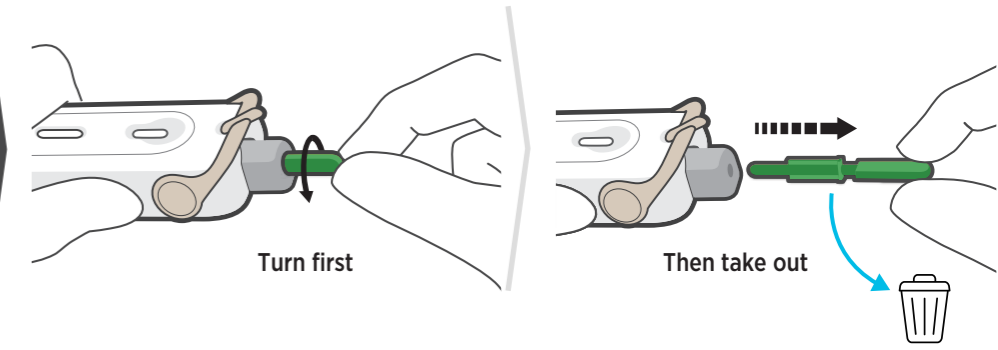
1 Wash and dry hands. Check expiry date before you open the foil pouch.



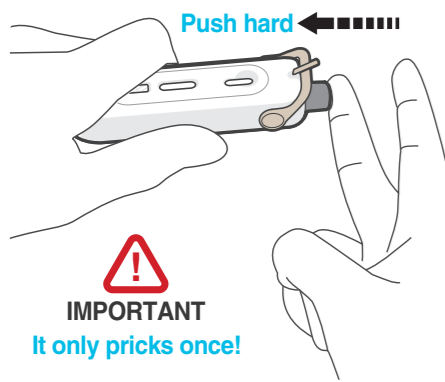
2 Massage your finger for 5 to 10 seconds.



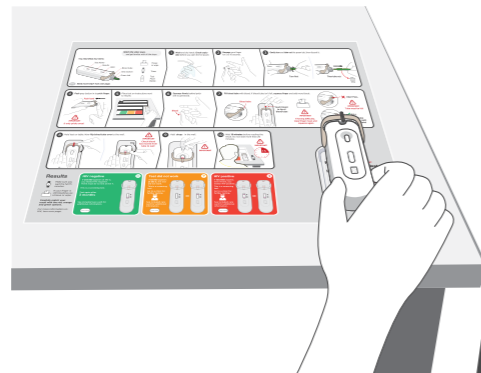
3 Gently turn and take out the green tab, then discard it.



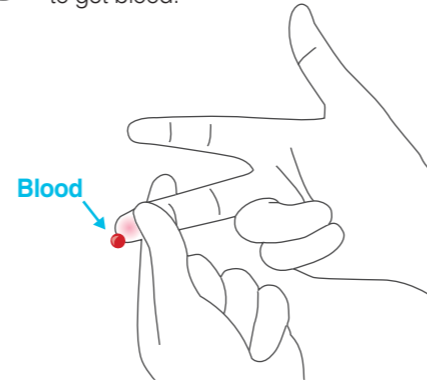
4 Push grey button in to prick finger.



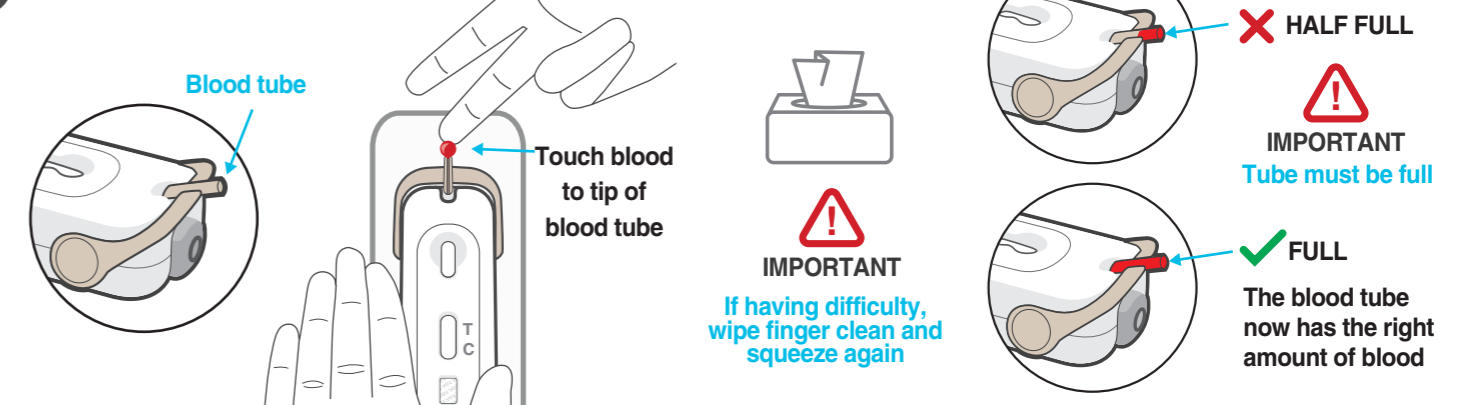
5 Place test on instructions next to results.



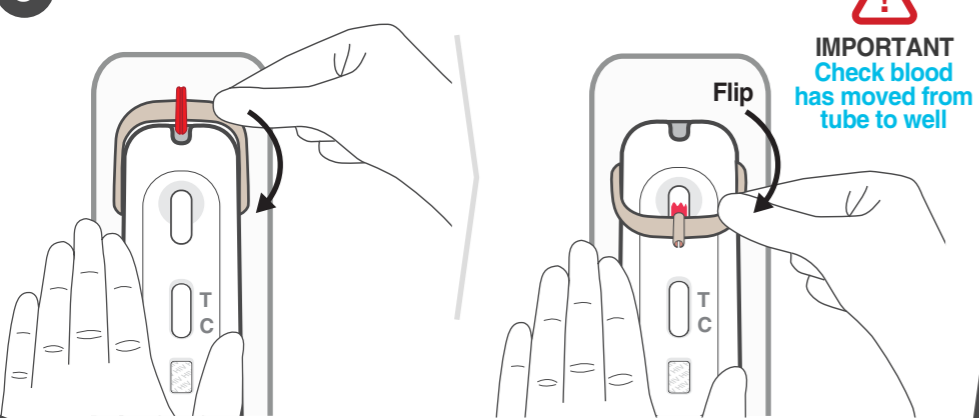
6 Squeeze firmly behind prick site to get blood.



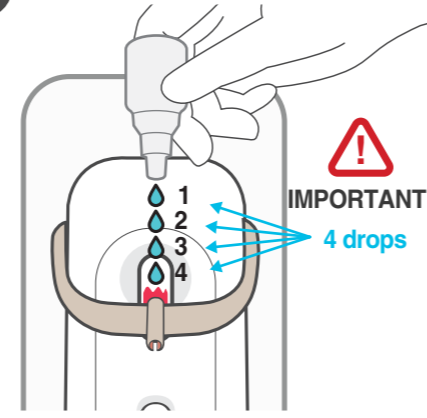
7 Fill blood tube with blood. If blood tube isn't full, squeeze finger and add more blood.



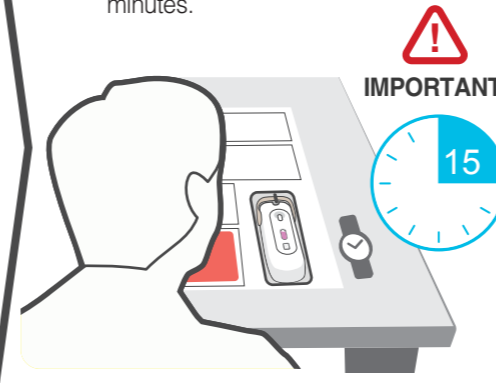
8 Hold test on table. Now flip blood tube over to the well.



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 **-**, **?** and **+** options.

For more information on HIV, turn over page.

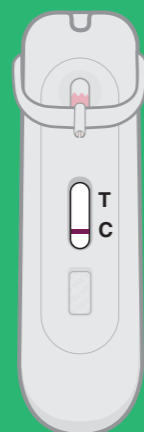
- HIV negative

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.



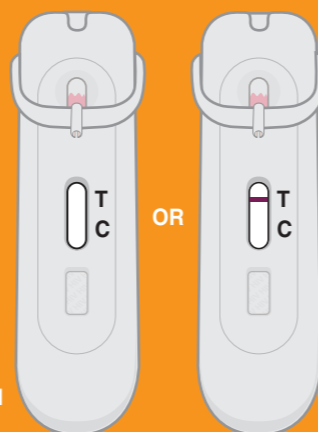
? Test did not work

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



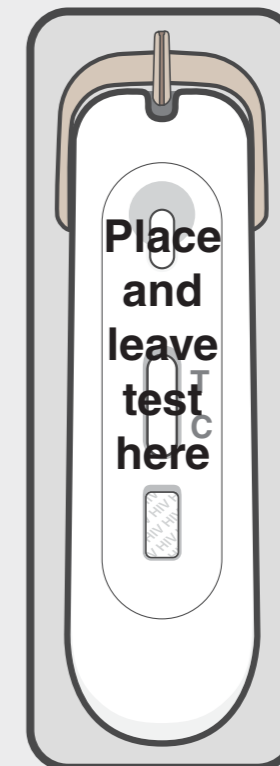
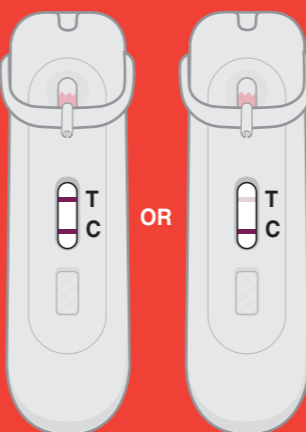
+ HIV positive

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?

Before You Start

Do not open the foil package until you have read the instructions and are ready to take the test. Use immediately upon opening.

Finger Prick

Can I get an infection from pricking my finger?

- * The test has an integrated sterile lancet for pricking the finger and creating a blood sample. The green sterility tab ensures that the lancet remains sterile before use.
- * If the test is completed per instructions by washing hands, there is minimal risk of infection from using the [Mylan HIV Self Test](#)

Having trouble removing the green sterility tab?

- * First turn the green sterility 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.
Note: It only pricks once!



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

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 2 types of Human Immunodeficiency Virus (HIV): 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.

The [Mylan HIV Self Test](#) is designed to detect these antibodies in human blood to determine infection by either virus type. This is a single-use screening test that gives a result in 15 minutes. If a positive result is given, this must be confirmed by a healthcare professional using a different type of test.

What is the "window period"?

After exposure to HIV, it can be 6 to 12 weeks before your body develops the antibodies detected by this test. This time is called the "window period". If you take an HIV self test during the window period, you may incorrectly get a negative result. If you believe you have recently been exposed to HIV, you are recommended to test again after the window period has passed.

What happens if my test result is NEGATIVE?

It is important to know if it has been more than 3 months since your last risk event. If it has, and you have performed the test correctly, then you are likely to be HIV negative. If it has been less than 3 months since your risk event, you will need to test again in 3 months. 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 able to live long, active and healthy lives. [The Mylan HIV Self Test](#) is a screening test and getting a positive test result does not necessarily mean that you have HIV. If the test result is positive, you need to go for follow up testing at a healthcare facility. Early diagnosis of HIV means treatment can start sooner. Refer to the enclosed **Care Card** or visit www.mylan.in/en/mylanhivselftest for more information about accessing follow-up testing.

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

What happens if my test doesn't work?

The test will not give a result if it is not performed correctly. You will need to repeat the test using a new test device. If you are unsure if you have performed the test correctly, please speak to your doctor or healthcare professional.

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

You should go to your doctor, HIV clinic or emergency department as soon as possible, and within 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.

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. If left untreated, HIV can lead to Acquired Immune Deficiency Syndrome (AIDS). There is no cure for HIV, or AIDS, but with correct medical treatment it can be managed as a non-life threatening condition. With early diagnosis and treatment, the life expectancy for someone with HIV can be similar to that of someone who does not have HIV.

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 important to know your status to help prevent passing the virus on to others.

How is HIV acquired or passed on?

Certain body fluids from a person who has HIV – including blood, breast milk, semen, rectal fluids and vaginal fluids – can transmit HIV. Transmission can occur if these fluids come into contact with a mucous membrane (found inside the rectum, vagina, penis or mouth) or damaged tissue, or are directly injected into the bloodstream (by a needle or syringe). HIV can also be transferred from an HIV positive mother to her child during pregnancy or childbirth. HIV risk events include:

- * Unprotected sex with someone who has HIV or whose HIV status is unknown.
- * Unprotected sex (vaginal or anal) with multiple partners.
- * Using non-sterile needles or injecting equipment.

HIV is NOT transmitted by casual contact (shaking hands, sharing a glass, etc.), kissing, saliva, tears, sweat, air or water.



Visit <http://www.mylan.in/en/mylanhivselftest> to watch an instructional video. If you have any specific questions, feedback, or suggestions email hivselftest-support@mylan.com

Summary of the Test

The [Mylan 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 [Mylan 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 [Mylan HIV Self Test](#) is intended to be used by untrained lay users in a private setting 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 - [Mylan 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.

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.

Disposal

To dispose of the [Mylan 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.

Test Performance

The [Mylan HIV Self Test](#) has been shown in laboratory testing to correctly identify 99.6% (1757/1764) of HIV negative samples (known as the test's specificity). Further, in in-field clinical evaluations conducted in Kenya and Australia it correctly identified 95.2% (866/910) of HIV negative samples when performed by first time self test users.

The [Mylan HIV Self Test](#) has also been shown in laboratory testing to correctly identify 99.6% (904/908) of HIV positive samples (known as the test's sensitivity). Of these samples, the test correctly detected 99.5% of samples with HIV-1 infection and 100% of samples with HIV-2 infection. Further, in in-field clinical evaluations conducted in Kenya it correctly identified 94.3%

(33/35) of positive samples when performed by first time self test users.

Testing was performed with all samples being cross-checked using a known accurate (CE-marked) laboratory test. Testing was performed in the laboratory (with CE-marked licensed sample sets) with samples being used from both high prevalence regions (South Africa) and low prevalence regions (Europe). The in-field clinical evaluations determined performance and usability of the test in the hands of 910 patients and were performed by the Kenya Medical Research Institute (Nairobi, Kenya) and an Australian based medical practice.

To ensure that other medical conditions (potentially interfering substances) did not affect the performance of the [Mylan HIV Self Test](#), samples of HIV negative blood were tested from people who had other conditions. These included (brackets show number of correct results, number of samples):

Pregnancy (200/200, 100%); Hospitalised patients (198/200, 99%); Rheumatic Factor (12/12, 100%); EBV (4/6, 66.7%); Malaria (6/6, 100%); Syphilis (5/6, 83.3%); HSV (5/5 100%); CMV (4/5, 80%); HBc (15/15, 100%); HBs (15/15, 100%); HCV (15/15, 100%); HTLV-I/II (10/10, 100%); HEV (10/10, 100%); Citrate (25/25, 100%); EDTA (25/25, 100%); Heparin (25/25, 100%); Recent Flu Vaccination (1/1, 100%); TB (1/1, 100%); Elevated Bilirubin (1/1, 100%); Icteric (1/1, 100%); Lipemic (1/1, 100%); Elevated Protein (1/1, 100%); Elevated

Triglycerides (1/1, 100%); Haemolysed Blood (1/1, 100%); E.coli (1/1, 100%); Haemoglobin (high or low) (1/1, 100%); Elevated IgG (1/1, 100%); ANA(1/1, 100%).

IVD 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

Australian Therapeutic Goods Administration (TGA) registration: ARTG 311989

Manufacturer
Atomo Diagnostics Pty. Ltd.
Level 2, 701-703 Parramatta Rd.
Leichhardt, NSW, 2040 Australia
atomodiagnosics.com

Distributor
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MIDC Industrial Estate, Taloja,
Panvel, District Raigad,
Maharashtra - 410208