WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: Mylan HIV Self Test
WHO reference number: PQDx 0320-090-00

Mylan HIV Self Test with product code **ARST001-03, ARST001-03-01, ARST001-03-02 and ARST001-03-03**, manufactured by **Atomo Diagnostics Ltd (formerly called Atomo Diagnostic Pty Ltd)**, **Rest of World regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 3 July 2019.

Summary of WHO Prequalification Assessment for Mylan HIV Self-Test

	Date	Outcome
Prequalification listing	3 July 2019	listed
Dossier assessment	26 May 2018	MR
Site inspection(s) of the quality management system	19 February 2018 Atomo Diagnostics Pty Ltd 3 September 2018 Lateral Flow Laboratories	MR
Product performance evaluation	8 August 2018	MR

MR: Meets Requirements

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Public report amendment	Summary of amendment	Date of report amendment
2.0	Amendment of the IFU on the intended use section and function of the procedural control line. Addition of a statement to clarify the limitation of the product performance evaluation and that these components were assessed as part of the dossier assessment.	2 September 2019
3.0	1. Add secondary foil packaging variant to Product Code (ARST001-03) by adding suffix numbers: ARST001-03-01, ARST001-03-02, ARST001-03-03 and ARST001-03-XX. 2. Change of the company name from Atomo Diagnostics Pty Ltd to Atomo Diagnostics Ltd.	10 June 2021

	3. Larger image of the Galileo cassette is placed on the front of the pouch. 4. Product description change to: -Easy-to-use integrated device -3rd Generation HIV Rapid Diagnostic Test -Gives an easy-to-read test result in 15 minutes. 4. Placeholder for the UDI added. 5. Addition of French and Portuguese languages.	
4.0	1) Change of street address for the Sydney office. 2) Removal of the disposal bag. 3) Addition of the manufacturing site details. 4) Addition of in-country registration information. 5) Change of URL. 6) Change the support email address. 7. Changed the address for the distributor from Mylan Pharmaceuticals Pvt Ltd Plot No. 1-A/2, MIDC Industrial Estate, Taloja, Panvel, District Raigad, Maharashtra – 410208 to Plot No.564/A/22, Road No.92, Jubilee Hills, Hyderabad, Hyderabad, Telangana, India, 500096."	22 August 2023
5.0	Corrected the public report by removing disposable bags from materials provided in the kit.	19 October 2023

Intended use

According to the claim of intended use by Atomo Diagnostics Ltd, "*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."

Assay description

According to the claim of assay description from Atomo Diagnostics Ltd "*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. A visible Control Line indicates that the diluent was added and migrated successfully, and that the test reagents*

are functioning correctly. The Test Line will only become visible if the applied sample contains antibodies to HIV".

Test kit contents

Component	1 test/kit (product code ARST001-03)	1 test/kit (product code ARST001-03-01)	1 test/kit (product code ARST001-03-02)	1 test/kit (product code ARST001-03-03)	1 test/kit (product code ARST001-03-XX
Instructions for Use (IFU)	1 IFU (Trilingual)	1 IFU (Trilingual)	1 IFU (English)	1 IFU (English)	IFU (English + regional language)
Mylan HIV Self Test (in a foil packet with desiccant)	1 device	1 device	1 device	1 device	1 device
Bottle of Test Fluid (Diluent)	1 bottle (2ml)	1 bottle (2ml)	1 bottle (2ml)	1 bottle (2ml)	1 bottle (2ml)
Alcohol wipe	1	1	1	1	1

Items required but not provided

- Box of tissues (or other clean, absorbent material).
- Timer (for example, a watch, clock or mobile phone) to track while waiting for results and Rubbish bin for disposal of the used test.

Storage

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

Shelf-life upon manufacture

18 months.

Warnings/limitations

Refer to the current version of the manufacturer's instructions for use attached to this public report.

Prioritization for prequalification

Based on the established eligibility criteria, the **Mylan HIV Self Test** was given priority for the WHO prequalification assessment.

Dossier assessment

Atomo Diagnostics Pty Ltd submitted a product dossier for **Mylan HIV Self-Test** as per the "*Instructions for compilation of a product dossier*" (PQDx_018 version 3). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 10 January 2019.

Commitments for prequalification

1. Measuring the range of the assay requires a revision to the IFU to include information that the product is susceptible to a high-dose hook effect at the next print run. This commitment was fulfilled, and the issue was closed.
2. Provide updated interim reports of the continuing shelf life study containing test results for each lot at September 2021 and October 2021. The reports were submitted and are under review.

Based on the product dossier screening and assessment findings, the Mylan HIV Self Test product dossier meets WHO prequalification requirements.

Manufacturing site inspection

A comprehensive inspection was performed at the sites of manufacture (Atomo Diagnostics Pty Ltd at Level 2, 701-703 Parramatta Road, Leichardt 2040 NSW, Australia and Lateral Flow Laboratories (LFL) at Unit 1 & 2, Greenwich Place, Capricorn Crescent, Capricorn Technology Park, Muizenberg,7945, South Africa) of **Mylan HIV Self Test** in February 2018 and September 2018 respectively as per the "*Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics*" (PQDx_014 version 4). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality.

The manufacturer's responses to the nonconformities found at the time of the inspection, including the final response provided on 15 January 2019, were accepted on 15 January 2019.

Based on the site inspections and corrective action plan review, the quality management system for **Mylan HIV Self Test** meets WHO prequalification requirements.

Product performance evaluation

Mylan HIV Self Test (Atomo Diagnostics Pty. Ltd) is an immunochromatographic assay for the detection of HIV-1/2 antibodies in human whole blood. A volume of 10 µl of capillary blood is needed to perform the assay. Mylan HIV Self Test is intended to be used by untrained lay users. This type of assay requires no sophisticated equipment. Reading of the results is done visually.

Mylan HIV Self Test was evaluated by WHO in the 1st and 2nd quarters of 2018 at the National Health Laboratory Quality Assurance and Training Centre, Dar el Salaam, Tanzania.

In this limited evaluation on a panel of 1013 capillary blood specimens collected from patients attending an HIV clinic and blood donors, compared to the reference assays (Murex HIV Ag/Ab Combination [DiaSorin S.p.A] and Genscreen ULTRA HIV Ag-Ab [Biorad Laboratories] in parallel; followed by INNO-LIA HIV I/II Score (Fujirebio)) performed on plasma, the following performance characteristics were obtained:

Performance characteristics in comparison with an agreed reference standard	
Sensitivity % (95% CI) (N=422)	99.8 (98.7-100)
Specificity % (N=591)	99.8 (99.1-100)
Invalid rate %	0
Inter-reader variability %	0

In addition, analytical performance characteristics were assessed using commercially available panels and the following results were obtained:

Analytical performance characteristics	
Sensitivity during seroconversion on 7 seroconversion panels in comparison with a benchmark assay (Murex HIV Ag/Ab, DiaSorin S.p.A)	Seroconversion sensitivity index of +0.3. Therefore, detection is 0.3 specimens later than the benchmark assay.
Analytical sensitivity on a mixed titer panel in comparison with an agreed reference standard	17 of 17 specimens were correctly classified.
HIV subtype detection using the WHO reference panel for anti-HIV	5/6 HIV-1 subtypes and HIV-2 detected. Specimen from individuals infected with HIV-1 Group O was not detected.

Key operational characteristics	
Validated specimen types (according to IFU)	Capillary whole blood
Number of steps	5 without precision pipetting required
Time to result	15 minutes
Endpoint stability	5 minutes (do not read more than 20 minutes after the addition of buffer)
Internal QC	Yes, the control line is on the test device.
In-use stability of reagents	Use immediately after opening.

Limitations:

1. In this performance evaluation, the Mylan HIV Self Test rapid tests were performed by trained laboratory technicians and not by untrained lay users as specified in the intended use.
2. All specimens used in the clinical performance evaluation were from the same geographical area.
3. All positive specimens in the clinical performance evaluation were positive for HIV-1, so the sensitivity of the Mylan HIV Self Test for the detection of HIV-2 could not be verified in this evaluation.

The performance of this product, when used by untrained self-testing users, as well as other aspects of performance from different geographical areas and on HIV-2 specimens, were assessed as part of the dossier assessment and meets the WHO prequalification requirements.

Labelling

1. **Labels**
2. **Instructions for use**

Labels

1.1 Product Pack (Outside)

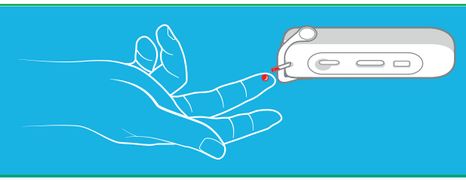
Mylan HIV Self Test

Single use
HIV screening test

Mylan

Gives an easy-to-read test result in 15 minutes

15



OPEN HERE

Watch the how-to video
https://ez2uzhiveselftest.com/

Inside this pack is a screening test for HIV that will give a quick and accurate result.

Contents:
- 1 x Mylan HIV Self Test
- Easy-to-follow instructions
- 1 x Bottle of test fluid
- 1 x Alcohol Wipe

This is a screening test for HIV antibodies and may not detect a recent infection. If you think you have been exposed to HIV recently and your test result is negative, you should test again in 3 months. Speak to a healthcare professional for more information.

MHST-PA-020 Rev 5.1

Print on demand with black ink (as applicable)

REF	XXXXX
LOT	XXXXX
2D DATA MATRIX	(01) XXXXXXXXXXXXXX (10) BATCH # (17) YYMMDD

YYYY-MM-DD

YYYY-MM-DD

Manufactured at
Lateral Flow Laboratories Pty. Ltd.
Capricorn Business Park, Unit 1&2
Greenwich Place, Capricorn Crescent
Mulzenburg, 7945, South Africa

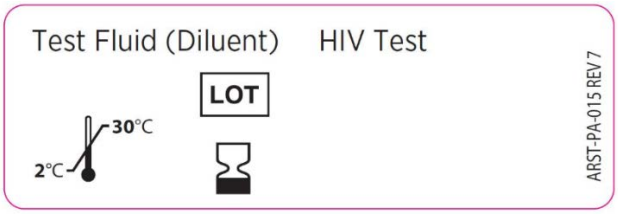
Manufacturer
Atomo Diagnostics Ltd.
Level 1, 3-5 George St.
Leichhardt, NSW, 2040, Australia
atomodiagnostics.com

Distributor
Mylan Parmaceuticals Pvt Ltd
Plot No.564/A/22, Road No.92,
Jubilee Hills, Hyderabad, Telangana,
India, 500096.

IVD

2°C 30°C

1.2 Test fluid (diluent label)



1.3 Foil pouch of Mylan HIV Self Test

Mylan HIV Self Test

Easy to use integrated device
3rd Generation HIV Rapid Diagnostic Test
Gives an easy-to-read test result in 15 minutes

Accurate | Safe | Convenient

Single use HIV screening test

Mylan

FRONT

Inside this pack is a screening test for HIV that will give a quick and accurate result.

Contents :

- 1 x Mylan HIV Self Test
- 1 x Bottle of test fluid
- 1 x Alcohol wipe
- Easy-to-follow instructions

This is a screening test for HIV antibodies and may not detect a recent infection. If you think you have been exposed to HIV recently and your test result is negative, you should test again in 3 months. Speak to a healthcare professional for more information.

Watch the test instruction video at :

https://www.ez2uzhivselftest.com

Follow us on :

#mylanez2uz

MHST-PA-022 Rev 3.1

Manufacturer
Atomo Diagnostics Ltd.
Level 1, 3-5 George Street,
Leichhardt, NSW 2040 Australia
atomodiagnostics.com

Distributed by
Mylan Pharmaceuticals Pvt Ltd
Plot No.564/A/22, Road No. 92,
Jubilee Hills, Hyderabad, Telangana
India – 500096

IVD | 2°C – 30°C

REF XXXXX | YYYY-MM-DD
LOT XXXXX | YYYY-MM-DD

2D DATA MATRIX
(01) GTIN
(10) BATCH #
(17) EXPIRY (YYMMDD)

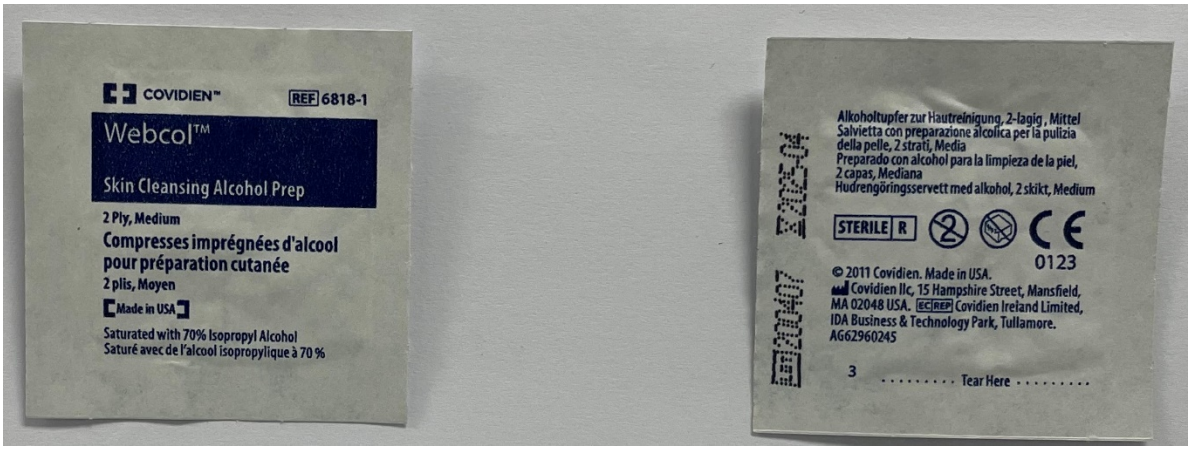
Manufactured at
Lateral Flow Laboratories Pty. Ltd.
Capricon Business Park, Unit 1&2,
Greenwich Place, Capricorn Crescent,
Mulzenburg, 7945, South Africa

Print on demand with black ink
(as applicable)

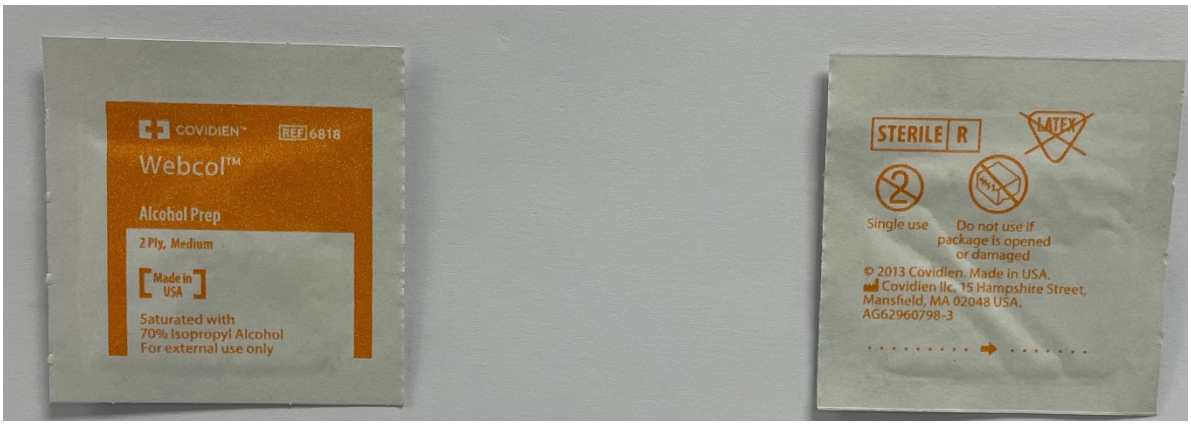
Mylan

BACK

1.3.1 Alcohol swab (REF 6818-1)



1.3.2 Alcohol swab (REF 6818)

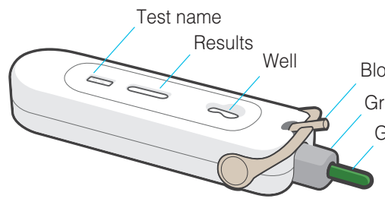


2.0 Instructions for use[1]

[1] English version of the IFU was the one that was assessed by the WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages

Watch the video: https://www.ez2uzhivselftest.com/

You need these items:



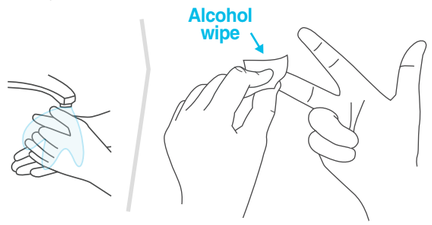
- Tissue or wipe
- Timer
- Test Fluid Bottle
- Alcohol Wipe
- Rubbish Bin for Disposal

EN **Need more help? Turn over page.**

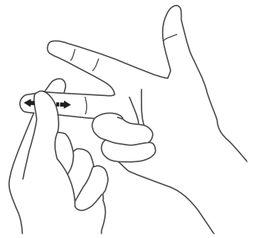
IMPORTANT: Do not open the foil package until you have read the instructions and are ready to take the test. Use immediately upon opening.

1 **Wash** and dry hands. **Clean** finger with alcohol wipe.

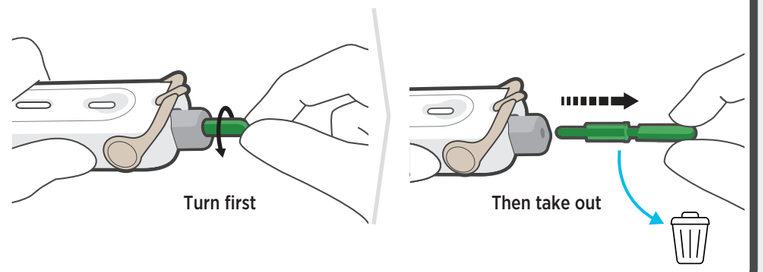
Check expiry date before you open the foil pouch.



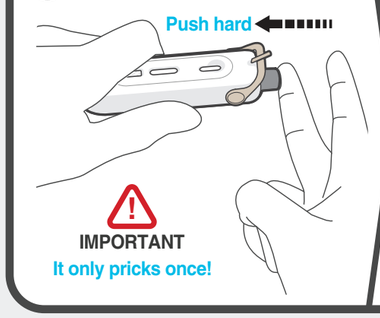
2 **Massage** your finger for 5 to 10 seconds.



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

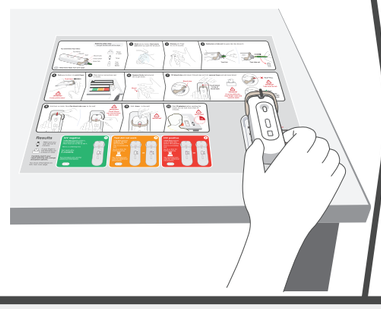


4 **Push** grey button in to **prick finger.**

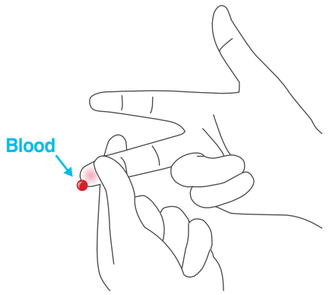


IMPORTANT
It only pricks once!

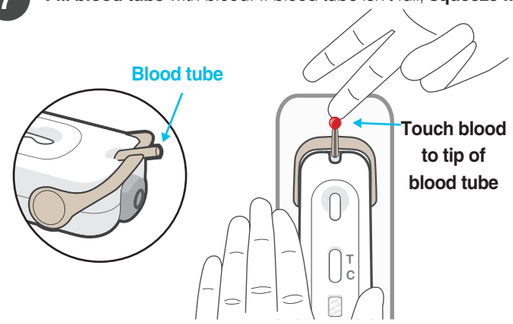
5 Place test on instructions next to results.



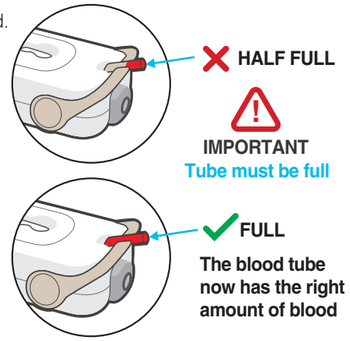
6 **Squeeze firmly** behind prick site to get blood.



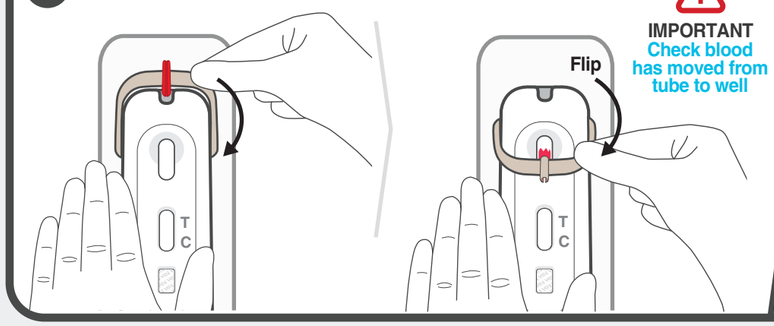
7 **Fill blood tube** with blood. If blood tube isn't full, **squeeze finger** and add more blood.



IMPORTANT
If having difficulty, wipe finger clean and squeeze again

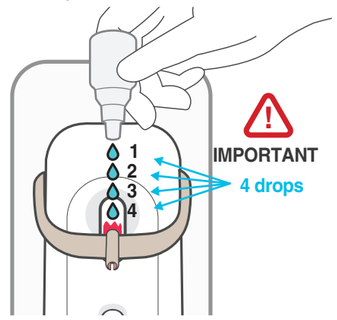


8 Hold test on table. Now **flip blood tube over** to the well.



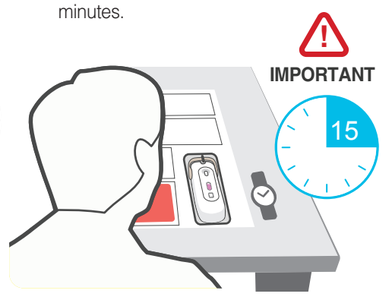
IMPORTANT
Check blood has moved from tube to well

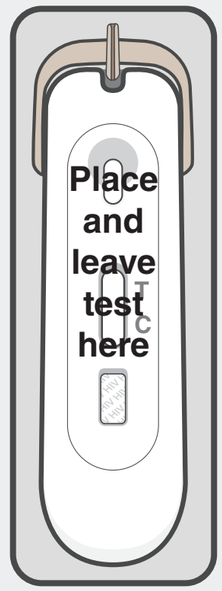
9 Add **4 drops** in the well.



IMPORTANT
4 drops

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





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

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.

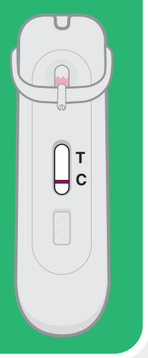
For more information on HIV, turn over page.

⊖ 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.

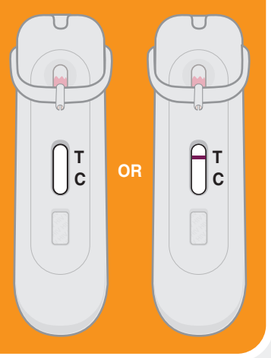
Test again after
3 months.



? Test did not work

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

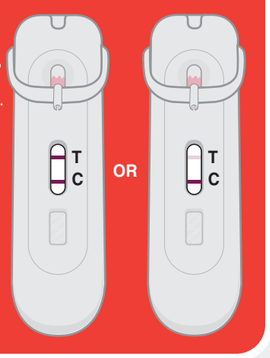
This is a screening test.
Go to a clinic for further testing.



⊕ 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.



MHST-OA-011 rev 7.1

Mylan | HIV SELF TEST

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 and use of the alcohol wipe, 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".

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.

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. Visit www.ez2uzhivselftest.com/ 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 https://www.ez2uzhivselftest.com/ to watch an instructional video. If you have any specific questions, feedback, or suggestions email hivselftest-support@viatris.com, or call +91 96865 85651

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. A visible Control Line indicates that the diluent was added and migrated successfully, and that the test reagents are functioning 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.

Materials Included

1 - Mylan HIV Self Test (in foil packet with desiccant)
1 - Bottle of Test Fluid (Diluent)
1 - Alcohol Wipe
Instructions for Use (IFU)

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.
- Rubbish bin for disposal of the used test.

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).
- Not suitable for use in testing children and infants

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 used Mylan HIV Self Test, place the test back into the product pack or secondary foil pouch. The packaging can then be closed and thrown away in a normal rubbish bin.

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 identity 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.

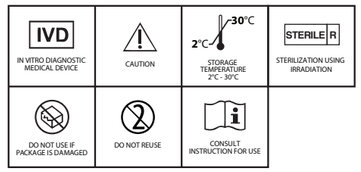
To ensure that other medical conditions (potentially interfering substances) did not affect the performance of the Mylan HIV Self Test, samples of HIV negative blood were tested from people who had other conditions. These included (brackets show number of correct results/ number of samples):

Pregnancy (200/200); Hospitalised patients (198/200); Rheumatic Factor (12/12); EBV (4/6); Malaria (6/6); Syphilis (5/6); HSV (5/5); CMV (4/5); HBc (15/15); HBs (15/15); HCV (15/15); HTLV-I/II (10/10); HEV (10/10); Citrate (25/25); EDTA (25/25); Heparin (25/25); Recent Flu Vaccination (1/1); TB (1/1); Elevated Albium (0/1); Elevated Bilirubin (1/1); Icteric (1/1); Lipemic (1/1); Elevated Protein (1/1); Elevated Triglycerides (1/1); Haemolysed Blood (1/1); E.coli (1/1); Haemoglobin (high or low) (1/1); Elevated IgG (1/1); ANA(1/1).

Samples of HIV negative blood from people who had other conditions were spiked with HIV positive plasma to ensure that performance of the test was not affected:

Rheumatic Factor (1/1), Elevated Albium (1/1); Elevated Bilirubin (1/1); Icteric (1/1); Lipemic (1/1); Elevated Protein (1/1); Elevated Triglycerides (1/1); Haemolysed Blood (1/1); E.coli (1/1); Haemoglobin (high or low) (1/1); Elevated IgG (1/1); ANA(1/1).

Mylan HIV Self Test is susceptible to a high dose hook effect. 6 out of 18 high reactivity samples tested indicated an increase in test Line intensity upon dilution. None of the samples showed false negative results.



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