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

<table>
<thead>
<tr>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prequalification listing</td>
<td>03-Jul-2019</td>
</tr>
<tr>
<td>Dossier assessment</td>
<td>26-May-2018</td>
</tr>
<tr>
<td>Site inspection(s) of quality management system</td>
<td>19-Feb-2018 Atomo Diagnostics Pty Ltd 3-Sept-2018 Lateral Flow Laboratories</td>
</tr>
<tr>
<td>Product performance evaluation</td>
<td>08-Aug-2018</td>
</tr>
</tbody>
</table>

MR: Meets Requirements

Report amendments and/or 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.

<table>
<thead>
<tr>
<th>Public report amendment</th>
<th>Summary of amendment</th>
<th>Date of report amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>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.</td>
<td>02-Sep-2019</td>
</tr>
<tr>
<td>3.0</td>
<td>1. Addition of secondary foil packaging variant to Product Code (ARST001-03) by adding suffix number: 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.</td>
<td>14-Jul-2021</td>
</tr>
</tbody>
</table>
3. Larger image of the Galileo cassette 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. Place holder for the UDI added.
5. Addition of French and Portuguese languages.

**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

<table>
<thead>
<tr>
<th>Component</th>
<th>1 test/kit (product code ARST001-03)</th>
<th>1 test/kit (product code ARST001-03-01)</th>
<th>1 test/kit (product code ARST001-03-02)</th>
<th>1 test/kit (product code ARST001-03-03)</th>
<th>1 test/kit (product code ARST001-03-XX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions for Use (IFU)</td>
<td>1 IFU (Trilingual)</td>
<td>1 IFU (Trilingual)</td>
<td>1 IFU (English)</td>
<td>1 IFU (English)</td>
<td>IFU (English + regional language)</td>
</tr>
<tr>
<td>Mylan HIV Self Test (in foil packet with desiccant)</td>
<td>1 device</td>
<td>1 device</td>
<td>1 device</td>
<td>1 device</td>
<td>1 device</td>
</tr>
<tr>
<td>Bottle of Test Fluid (Diluent)</td>
<td>1 bottle (2ml)</td>
<td>1 bottle (2ml)</td>
<td>1 bottle (2ml)</td>
<td>1 bottle (2ml)</td>
<td>1 bottle (2ml)</td>
</tr>
<tr>
<td>Alcohol wipe</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Disposal bag</td>
<td>1 bag</td>
<td>1 bag</td>
<td>1 bag</td>
<td>1 bag</td>
<td>1 bag</td>
</tr>
</tbody>
</table>

**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.

**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 immediately upon opening.

**Shelf-life upon manufacture**
18 months.

**Warnings/limitations**
Refer to current version of manufacturer’s instructions for use.

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

Based on the product dossier screening and assessment findings, the product dossier for **Mylan HIV Self Test** 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, Leichhardt 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:

<table>
<thead>
<tr>
<th>Performance characteristics in comparison with an agreed reference standard</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity % (95% CI) (N=422)</td>
<td>99.8 (98.7-100)</td>
</tr>
<tr>
<td>Specificity % (N=591)</td>
<td>99.8 (99.1-100)</td>
</tr>
<tr>
<td>Invalid rate %</td>
<td>0</td>
</tr>
<tr>
<td>Inter-reader variability %</td>
<td>0</td>
</tr>
</tbody>
</table>

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

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

### Key operational characteristics

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validated specimen types (according to IFU)</td>
<td>Capillary whole blood</td>
</tr>
<tr>
<td>Number of steps</td>
<td>5 without precision pipetting required</td>
</tr>
<tr>
<td>Time to result</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Endpoint stability</td>
<td>5 minutes (do not read more than 20 minutes after addition of buffer)</td>
</tr>
<tr>
<td>Internal QC</td>
<td>Yes, control line on the test device.</td>
</tr>
<tr>
<td>In-use stability of reagents</td>
<td>Use immediately after opening</td>
</tr>
</tbody>
</table>

### 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 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 Test fluid (diluent label)

1.2 Foil pouch of Mylan HIV Self Test

1.3. Secondary pouch label
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

Teste de Diagnóstico de VIH Rápido de 3ª Geração
Dispositivo integrado fácil de utilizar
Donne un résultat de test facile à lire en 15 minutes

Test de diagnostic rapide du VIH de 3ème génération
Dispositif intégré facile à utiliser
Resultado do teste obtido em 15 minutos

Accurate | Safe | Convenient
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 Easy-to-follow instructions
- 1 x Bottle of test fluid
- 1 x Discreet disposal bag
- 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.

**Conteúdo:**
- 1 x Kit de Autodiagnóstico do VIH da Mylan
- 1 x Instruções fáceis de seguir
- 1 x Frasco com fluido de teste
- 1 x Limpeza com álcool
- 1 x Saco discreto para eliminação

Este é um teste de rastreio de anticorpos do VIH e pode não detectar uma infecção recente. Se você acredita ter estado exposto(a) recentemente ao VIH e o resultado do seu teste é negativo, paseadas 3 meses deve fazer o teste novamente. Fale com um profissional de saúde para mais informações.

**Contenu:**
- 1 x Autotest du VIH Mylan
- 1 x Instructions facile à suivre
- 1 x Bouteille de liquide d’essai
- 1 x Lingette d’alcool
- 1 x Sac à déchets discret

Ceci est un test de dépistage des anticorps du VIH et ne peut ne pas détecter une infection récente. Si vous pensez avoir été exposé récemment au VIH et que le résultat de votre test est négatif, vous devriez effectuer un autre test dans 3 mois. Parlez à un professionnel de santé pour plus d’informations.

Watch the test instruction video at:
https://www.mylanez2uz.com

Follow us on:
#mylanez2uz

Manufactured by
Mylan Pharmaceuticals Pvt Ltd
Plot No. 1-A/2, MIDC Industrial Estate, Taloja, Panvel, District Raigad, Maharashtra – 410208

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

Distributed by
Mylan Pharmaceuticals Pvt Ltd
Plot No. 1-A/2, MIDC Industrial Estate, Taloja, Panvel, District Raigad, Maharashtra – 410208

Do not use if package is broken
Ne pas utiliser si le paquet est endommagé.
Não usar se a embalagem estiver danificada

PLACEHOLDER FOR UDI BARCODE AND INFORMATION 20MM X90MM
1.4.1 Alcohol swab (REF 6818-1)

![Image of Alcohol swab (REF 6818-1)]

1.4.2 Alcohol swab (REF 6818)

![Image of Alcohol swab (REF 6818)]
1.5 Outside packaging labels

1.5.1 English label
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.

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

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

Manufacturer: ARST001-03-03

Do not use if package is broken

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

Mylan HIV Self Test

Single use HIV screening test

MHST-PA-020 Rev 4

OPEN HERE

http://www.mylan.com
1.5.2 Trilingual label
Este é um teste de rastreio de anticorpos do VIH e pode não detetar uma infeção recente. Se pensa ter estado exposto(a) recentemente ao VIH e o resultado do seu teste é negativo, passados 3 meses deve fazer o teste novamente. Fale com um profissional de saúde para mais informações.

Conteúdo:
- 1 x Kit de Autodiagnóstico do VIH da Mylan
- 1 x Instruções fáceis de seguir
- 1 x Frasco com fluido de teste
- 1 x Limpe com álcool
- 1 x Saco discreto para eliminação

A embalagem contém um teste de rastreio do VIH com resultado rápido e preciso.

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

Resultado do teste obtido em 15 minutos

Donne un résultat de test facile à lire en 15 minutes

Mylan HIV Self Test Single use
HIV screening test

Atomo Diagnostics Ltd.
Level 2, 701-703 Parramatta Rd.
Leichhardt, NSW, 2040 Austrália
atomodiagnostics.com

Manufacturer
Mylan Pharmaceuticals Pvt Ltd
Plot No. 1-A/2, MIDC Industrial Estate,
Taloja, Panvel, District Raigad,
Maharashtra – 410208 Índia

Distributor

Do not use if package is broken
Não use se a embalagem estiver danificada
Ne pas utiliser si le paquet est endommagé

Ceci est un test de dépistage des anticorps du VIH et peut ne pas détecter une infection récente. Si vous pensez avoir été exposé récemment au VIH et que le résultat de votre test est négatif, vous devriez effectuer un autre test dans 3 mois. Parlez à un professionnel de santé pour plus d'informations.

Contenu :
- 1 x Autotest du VIH Mylan
- 1 x instructions facile à suivre
- 1 x Bouteille de liquide d'essai
- 1 x Lingette d'alcool
- 1 x Sac à déchets discret

À l'intérieure de ce paquet est un test de dépistage du VIH qui donnera un résultat rapide et exact.
2.0 Instructions for use

1 English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
Watch the video: https://www.mylan2ez.com/

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.

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.

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

IMPORTANT: It only pricks once!

IMPORTANT: Check blood has moved from tube to well

IMPORTANT: Check blood to tip of blood tube

IMPORTANT: Tube must be full

IMPORTANT: The blood tube now has the right amount of blood

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

Results

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.

You need these five items:

- Test name
- Results
- Blood tube
- Grey button
- Green sterility tab
- Alcohol wipe
- Tissue or wipe
- Timer
- Test Fluid Bottle
- Alcohol Wipe

Wash and dry hands. Clean finger with alcohol wipe. Check expiry date before you open the foil pouch.

Push grey button in to prick finger. Push hard.

Massage your finger for 5 to 10 seconds.

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

Place test on instructions next to results.

Add 4 drops in the well.

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

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

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

Push grey button in to prick finger.

IMPORTANT: It only pricks once!

IMPORTANT: Check blood has moved from tube to well

IMPORTANT: Check blood to tip of blood tube

IMPORTANT: Tube must be full

IMPORTANT: The blood tube now has the right amount of blood

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

For more information on HIV, turn over page.

IMPORTANT: Check expiry date before you open the foil pouch.

Test Fluid Bottle

Tissue or wipe

Timer

Test Fluid Bottle

Alcohol Wipe

Alcohol Wipe

Sterile Wipe

ISOPROPYL ALCOHOL WIPE

70%

RATIONALE

RATIONALE

RATIONALE

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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 lancelet for pricking the finger and creating a blood sample. The green sterility tab ensures that the lancet remains sterile until the test is used.
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?
At 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!

Completing the Test
What if the blood does not move from the tube to the well?
If the test is done correctly, make sure the tubes are in the correct position. If the test is done incorrectly, please speak to your doctor or healthcare professional.

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 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 blood tube to access to the tip.
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.

Materials Included

Instrustions for Use (FU)
• Mylan HIV Self Test (in foil packet with desiccant)
• Bottle of Test Fluid (Diluent)
• Alcohol Wipe
• Disposal bag

Items NOT Included but required
Skin lesions or other (all 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 to put with a fast food restaurant.
Not suitable for people already diagnosed as HIV positive.

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 healthcare 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 tabs 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.

About Your Result
About HIV

Need Help with the Test?

What is HIV?
HIV stands for Human Immunodeficiency Virus. It is a virus that targets the immune system and over time, if left untreated, results in Acquired Immunodeficiency Syndrome (AIDS). AIDS is a life-threatening condition caused by a virus (HIV) and AIDS is the result of HIV infection. If left untreated, HIV can lead to Acquired Immunodeficiency Syndrome (AIDS), which is a life-threatening condition caused by a virus (HIV) and AIDS is the result of HIV infection. If left untreated, HIV can lead to AIDS.

About Your Result
What happens if my test result is POSITIVE?
If you are HIV positive, you need to consult a healthcare professional to manage your status. You will need to take action to prevent passing the virus on to others.

Important: Retest after 3 months.

Restrictions on use
Not suitable for people with a fear of needles.

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Restrictions on use
Not suitable for people with a fear of needles.
Results

**HIV negative**
- Two lines appear in window.
- Result is valid for 3 months.
- If having difficulty, watch our video: https://www.mylanez2uz.com

**HIV positive**
- One line appears in window.
- Re-test in 3 months.
- Test did not work.

Test did not work
- No lines appear in window.
- Try again after 3 months.
- If it still does not work, see your doctor.

For more information see page 3.

**IMPORTANT**
- Place test on clean, flat surface.
- Do not touch test tip or tip of blood tube.
- Do not open Blood tube before reading the result.

Well done! You have successfully completed the test.

You need these five items:
- Test
- Blood tube
- ISOPROPYL Alcohol Wipe
- Tissue or wipe
- Stérilé

Check expiry date of Blood tube before reading the result.

Ceci est un test de rastreage.

Le test n'a pas marché
- Si l'apparaît au C, le test n'a pas fonctionné.

Si ne fonctionne pas, essayez à nouveau.

Si résultats ne sont pas valides, essayez à nouveau après 3 mois.

S'il n'est pas fonctionné, consultez un médecin.

Pour plus de renseignements sur le VIH, virez à la page suivante.
Before You Start

Peel off the peelable film. The test is only valid when the film is peeled off. Do not use the test if the film is damaged. To ensure that other medical conditions (potentially interfering with the test) do not affect the result, please consult a healthcare provider.

Priming the Tube

Rearrange the tube so that the delivery tip is pointing upwards. Use the provided alcohol wipes to ensure the tube is sterile. Do not use any other substances or liquids to prime the tube.

About Your Result

The test result is qualitative (“your test is positive” or “your test is negative”). If the control band does not appear on the test device, the test is invalid even if the test is correct. If the control band appears, the test result is positive. The test result can be used to inform your healthcare provider of your HIV status.

What happens if my test result is POSITIVE?

If your test result is positive, you should be referred to a healthcare provider to confirm the result. Treatment with antiretroviral medication is necessary to prevent further transmission and progression of the disease. Your healthcare provider will provide a detailed explanation of your test result and recommend appropriate actions.

Full disclosure of your test result is required to your healthcare provider and other relevant parties. You may also be required to inform your sexual partners if they are at risk.

What happens if my test result is NEGATIVE?

If your test result is negative, you should be informed of the result and encouraged to continue regular testing. This is because HIV can still be present in the body for several weeks after infection, and the test may not be able to detect it.

If you have tested negative for HIV, you should consider behavior modification to reduce the risk of future infections. This includes regular testing, safe sexual practices, and avoiding sharing needles or equipment with others.

Conclusion

You have completed your test. Remember to follow your healthcare provider’s instructions for further testing and treatment. Thank you for using the Mylan HIV Self Test.