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, manufactured by Atomo Diagnostics 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>
</tbody>
</table>
**Intended use**

According to the claim of intended use from by Atomo Diagnostics Pty 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 Pty 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 tests (product code ARST001-003)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions for Use (IFU)</td>
<td>1 IFU</td>
</tr>
<tr>
<td>Mylan HIV Self Test (in foil packet with desiccant)</td>
<td>1 device</td>
</tr>
<tr>
<td>Bottle of Test Fluid (Diluent)</td>
<td>1 bottle (2ml)</td>
</tr>
<tr>
<td>Alcohol wipe</td>
<td>1</td>
</tr>
<tr>
<td>Disposal 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 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.
2. Provide updated interim reports of the continuing shelf life study containing test results for each lot at December 2019, January 2020, September 2021 and October 2021

Evidence for the measuring range commitment was submitted to WHO and is under review. 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:

<table>
<thead>
<tr>
<th><strong>Analytical performance characteristics</strong></th>
<th></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>

<table>
<thead>
<tr>
<th><strong>Key operational characteristics</strong></th>
<th></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
1.3.1 Front of alcohol swab

![Front of alcohol swab image]

1.3.2 Back of the alcohol swab

![Back of alcohol swab image]
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: http://www.mylan.in/en/mylanhivselftest

You need these five items:
- Test name
- Results
- Well
- Blood tube
- Grey button
- Green sterility tab
- Tissue or wipe
- Timer
- Test Fluid Bottle
- Alcohol wipe

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

See included care card for additional information.

For more information on HIV, turn over page.

Results

HIV negative
- 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.

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.

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

See included care card for additional information.

For more information on HIV, turn over page.

IMPORTANT
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.

IMPORTANT
If no line appears at the C, the test did not work.
- This is a screening test.
- Go to a clinic for further testing.

IMPORTANT
If two lines appear, even if faint, you tested HIV positive.
- This is a screening test.
- Go to a clinic for further testing.

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

See included care card for additional information.

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Content:

**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 a screening test and getting a positive result does not necessarily mean that you have HIV. If the last result is positive, you need to go to follow up testing to determine if you have HIV. The diagnosis of HIV means treatment can start soon. Visit your new mylan HIV marketplace 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?**

If you performed the test correctly, you are very likely to be HIV negative. If the test result is positive, you need to test again. The Mylan HIV Self Test has been shown in clinical evaluations to conduct in Kenya it can correctly detect 99.5% of samples with HIV-1 (93/94), 93.3% (33/35) of positive samples when performed by first time self test users.

Testing was performed with all samples being tested (CE-marked) laboratory test. Testing was performed on a field, foil packet (with marked (licensed sample sets) with samples being used from a confirmed positive sample collection) and low prevalence regions (Europe). In the field clinical evaluations determined performance and variability of results and were performed by the Kenya Medical Research Institute (Mainland) and an Australian based medical practice.

To ensure that other medical conditions (potentially interfering substances) did not affect the performance of the test, 200 negative blood samples of HIV negative blood were tested from people who had other conditions. Those included (brackets show number of correct results/interfering positives):

- Pregnancy (200/200)
- Rheumatic Factor (1/1)
- Elevated Albium (1/1); Elevated Bilirubin (1/1); Elevated IgG (1/1); ANA(1/1).
- Haemolysed Blood (1/1); E.coli (1/1); Haemoglobin (high or low) (1/1); Elevated IgG (1/1); ANA(1/1).
- Haemoglobin (904/908) of HIV positive samples (known as the test’s sensitivity). Of these samples, the test correctly detected 99.6% of samples with HIV-1 infection and 99.2% of samples with HIV-2 infection. Further, in-field clinical evaluations conducted in Kenya it can correctly detect 99.5% of samples with HIV-1 (93/94), 93.3% (33/35) of positive samples when performed by first time self test users.

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- Haemolysed Blood (1/1); E.coli (1/1); Haemoglobin (high or low) (1/1); Elevated IgG (1/1); ANA(1/1).

HIV test. It is important to know your status to help prevent passing the virus on to others.

**About HIV**

**HIV** stands for Human Immunodeficiency Virus. It is a virus that targets the immune system, weakening it over time reduces the body’s ability to fight infection. It left untreated, HIV can lead to Acquired Immune Deficiency Syndrome (AIDS). There is no cure for HIV, 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. This is 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 occurs if these fluids come in contact with a mucous membrane (found inside the rectum, vagina or penis) or damaged tissue, or are directly injected into the bloodstream (by a needle or syringe). HIV can also be transmitted from an HIV positive mother to her baby 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-shared needles or injecting equipment.

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

**Important: Retest after 3 months.**

**Limitations of the Test**

- Not suitable for use in testing children and infants
- May not detect HIV infections that have occurred within the last 3 months
- Not suitable for testing in children and infants
- Avoid eye/kin contact with the test fluid
- Do not use if test fluid is not of the foil packet with test fluid
- Do not use if the foil packet is damaged (e.g. torn, hole or the seal is broken) or open
- Do not use if test fluid has been tampered with
- Do not use if test fluid bottle has been opened or is leaking

**Summary of the Test**

The Mylan HIV Self Test is comprised of a paper test strip, a pipe, a pipette, a lancet and a test fluid. 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 on the test strip indicate a positive result. The Mylan HIV Self Test has been shown in clinical evaluations conducted in Kenya it can correctly detect 99.5% of samples with HIV-1 (93/94), 93.3% (33/35) of positive samples when performed by first time self test users.

If you took an HIV self test during the “window period”, you will need to test again after the window period has passed.

Not suitable for people already diagnosed as HIV positive.

- Do not use in testing children and infants
- Avoid eye/kin contact with the test fluid
- Do not use if test fluid is not of the foil packet with test fluid
- Do not use if the foil packet is damaged (e.g. torn, hole or the seal is broken) or open
- Do not use if test fluid has been tampered with
- Do not use if test fluid bottle has been opened or is leaking