WHO Prequalification of Diagnostics Programme
PUBLIC REPORT

Product: INSTI HIV Self Test
WHO reference number: PQDx 0002-002-01

INSTI HIV Self Test, with product code 90-1071, manufactured by bioLytical Laboratories Inc., Rest-of-World (ROW) regulatory version, was accepted for the WHO list of prequalified diagnostics and was listed on 30 November 2018.

Summary of prequalification status for INSTI HIV Self-Test

<table>
<thead>
<tr>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>PQ listing</td>
<td>30-Nov-2018</td>
</tr>
<tr>
<td>Dossier assessment</td>
<td>15-Aug-2013</td>
</tr>
<tr>
<td>Inspection status</td>
<td>21 – 23-Nov-2016</td>
</tr>
<tr>
<td>Laboratory evaluation</td>
<td>13-Jun-2013</td>
</tr>
<tr>
<td>Labelling accepted</td>
<td>27-Nov-2018</td>
</tr>
<tr>
<td>Change reviewed</td>
<td>27-Nov-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>Addition of an intended use specific for HIV self-testing (INSTI HIV Self Test). The new configuration was adapted from their professional use product (INSTI HIV-1/HIV-2 Antibody Test) for which a WHO prequalification assessment has already taken</td>
<td>27-Nov-2018</td>
</tr>
</tbody>
</table>

place. Additional data was generated to meet requirements set out in the WHO Technical Specifications Series document TSS-1 Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing.²

<table>
<thead>
<tr>
<th></th>
<th>Updates in the instructions for use of the product</th>
<th>06-Nov-2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>Correction of WHO reference number on the header of the public report from PQDx 0002-002-00 to PQDx 0002-002-01.</td>
<td>30-Aug-2021</td>
</tr>
</tbody>
</table>

**Intended use:**³

According to manufacturer’s claim, “INSTI HIV Self Test is a single use in vitro test that is used as a self-test for the detection of antibodies to HIV-1 and HIV-2 in infected individuals using a drop of human fingerstick blood.”

**Assay description:**

According to manufacturer’s claim, “INSTI HIV Self Test is a qualitative immunoassay that uses blood to detect HIV-1 and HIV-2 antibodies. The test produces a result in the form of either one dot (control dot) or two dots (control and test dots). The control dot is our built-in control feature that appears if you have performed the test correctly. A test dot will only be visible if the sample contains antibodies to HIV”.

**Test kit contents:**

The INSTI HIV Self Test is packaged as single test kit with product code 90-1071. One test kit will contain materials and test components for single use only.

<table>
<thead>
<tr>
<th>Product code</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>90-1071</td>
<td>1 x Blotted Membrane Unit (BMU)</td>
</tr>
<tr>
<td></td>
<td>1 x 1.5 mL Sample diluent bottle (Bottle 1)</td>
</tr>
<tr>
<td></td>
<td>1 x 1.5 mL Colour developer bottle (Bottle 2)</td>
</tr>
<tr>
<td></td>
<td>1 x 1.5 mL Clarifying solution bottle (Bottle 3)</td>
</tr>
<tr>
<td></td>
<td>1 x Sterile single-use lancet</td>
</tr>
<tr>
<td></td>
<td>1 x Adhesive bandage</td>
</tr>
<tr>
<td></td>
<td>1 x Instructions for Use (IFU)</td>
</tr>
<tr>
<td></td>
<td>1 x Alcohol swab</td>
</tr>
</tbody>
</table>

² [http://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf?sequence=1)

³ This product is one that uses Protein A to detect human IgG antibodies. Protein A is also able to detect other classes of human antibody (IgA, IgD, IgE and IgM) but not as reliably as it does IgG. This product has been prequalified with respect to its ability to detect human IgG antibodies. Any claim to detect other types of antibodies on this kind of product has not been validated based on WHO prequalification requirements.
Storage:
The test kit should be stored at 2 to 30 °C.

Shelf-life upon manufacture:
15 months.

Warnings:
- Do not use if the test device pouch is broken.
- Do not use if you:
  - have a bleeding disorder
  - are on Antiretroviral Therapy (ART)
- Blood can transmit infectious diseases. Clean up spills.

Limitations:
- Refer to current version of manufacturer’s instructions for use
Labelling

1. Labels
2. Instructions for use
1. Labels

Pouch 51-1266
Solution 1 bottle label 51-1040

Solution 2 bottle label 51-1041
Solution 3 bottle label 51-1042

Test device pouch 51-1061
2. Instructions for use

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4 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.
**Preparation**

1. Open test device pouch.
2. Place test device on a flat surface.
3. Place lancet on the side of finger tip.
4. Rub finger until warm.

**Step 1: Collect Blood**

1. Rub finger to create a LARGER drop of blood.
2. Place lancet on the side of finger tip.
3. Twist off tip and put aside.
4. Place test device on a flat surface.
5. Remove cap of Bottle 1.
6. Place on flat surface.

**Step 2: Test**

1. Shake and pour all liquid.
2. Let 1 drop FALL into Bottle 1.
3. Twist on cap of Bottle 1.
4. Shake and pour all liquid.
5. Shake and pour all liquid.
6. Shake and pour all liquid.

**Step 3: Read Result**

1. Read your result within 5 minutes. If you are unsure of your result, go to clinic for confirmatory testing.
2. Positive
3. Negative
4. Invalid

**Dispose**

1. For in vitro diagnostic use
2. Sterilization using irradiation
3. Catalogue Number
4. Lot number
5. Manufactured by

**Questions and Answers**

**About the Test**

1. How does the INSTI HIV Self Test work?
2. How early can this test detect HIV?
3. Can any medication or medical conditions affect the result?
4. What happens if my test result is positive?
5. What happens if my test result is negative?
6. What happens if my test result is invalid?
7. How do I make sure I get enough blood?
8. What happens if I spill some of the contents of Bottle 1, Bottle 2 or Bottle 3 outside the test device?
9. Useful as a self-test for the detection of antibodies to HIV-1 and HIV-2 in infected individuals using a drop of human fingerstick blood.

**Test Procedure**

1. How do I make sure I get enough blood?
2. Perform the test procedure.
3. How do I make sure I get enough blood?
4. Perform the test procedure.
5. How do I make sure I get enough blood?
6. Perform the test procedure.
7. How do I make sure I get enough blood?
8. Perform the test procedure.
9. How do I make sure I get enough blood?
10. Perform the test procedure.

**Test Results**

1. How do I make sure I get enough blood?
2. How do I make sure I get enough blood?
3. How do I make sure I get enough blood?
4. How do I make sure I get enough blood?
5. How do I make sure I get enough blood?
6. How do I make sure I get enough blood?
7. How do I make sure I get enough blood?
8. How do I make sure I get enough blood?
9. How do I make sure I get enough blood?
10. How do I make sure I get enough blood?

**General**

1. What is HIV and AIDS?
2. How are results interpreted?
3. How many results can you see at a time?
4. What are the steps involved in conducting a test?
5. How do you conduct a test?
6. How do you conduct a test?
7. How do you conduct a test?
8. How do you conduct a test?
9. How do you conduct a test?
10. How do you conduct a test?