WHO Prequalification of Diagnostics Programme
PUBLIC REPORT

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

Abstract

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 amended for INSTI HIV Self Test</td>
<td>30 November 2018</td>
</tr>
<tr>
<td>PQ listing</td>
<td>30 November 2018</td>
</tr>
<tr>
<td>Labelling accepted</td>
<td>27 November 2018</td>
</tr>
<tr>
<td>Change reviewed*</td>
<td>27 November 2018</td>
</tr>
</tbody>
</table>

MR: Meets Requirements

*Change notification

In 2018, bioLytical™ Laboratories submitted a change notification to their prequalified product INSTI HIV-1/HIV-2 Antibody Test to introduce a new configuration with 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 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.¹

Commitments:
N/A

¹ http://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf;jsessionid=E2718EC36EFD314EFE87E902244528E1?sequence=1
Summary of WHO prequalification assessment for INSTI HIV-1/HIV-2 Antibody Test

<table>
<thead>
<tr>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 July 2018</td>
<td>Fulfilment of dossier related commitments and Update to reflect latest inspection information</td>
</tr>
<tr>
<td>22 March 2018</td>
<td>Delisting of the product code 90-1012 INSTI HIV-1/HIV-2 Antibody Test (singles test configuration) due to general foreseeable risk of individually packaged tests being misused as self-tests.</td>
</tr>
</tbody>
</table>

Status on PQ list: 29 August 2013
Dossier assessment: 15 August 2013
Inspection status: 21 – 23 November 2016
Laboratory evaluation: 13 June 2013

MR: Meets Requirements

Intended use:
According to manufacturer’s claim “The INSTI HIV Self-Test is intended for use by untrained lay users as a self-test to detect HIV-1 and HIV-2 antibodies using a single drop of human fingerstick blood.”

Assay procedure:
“Reagents required to conduct the test include Sample Diluent (Solution 1), Colour Developer (Solution 2) and Clarifying Solution (Solution 3). The test is performed by adding one free falling drop of blood obtained by finger prick to the vial of Sample Diluent, which lyses the blood cells. This specimen/diluent solution is then poured into the well of the Membrane Unit. HIV antibodies, if present in the specimen, are captured in the form of test dot on the Membrane Unit. Colour Developer is then added to the Membrane Unit which reacts with the captured antibodies to generate a distinct blue dot at the location of the control spot and, in the case that HIV antibodies are present in the specimen, a blue dot also appears at the location of the test spot on the membrane. In the final step, Clarifying Solution is added to the membrane to decrease background color in order to make the control and test dots more distinct.”

Assay description:
According to manufacturer’s claim “The INSTI® HIV Self-Test, 90-1071 is a single use, rapid, flow-through in vitro qualitative immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in human fingerstick whole
blood. The test consists of a nitrocellulose filtration membrane positioned atop an absorbent material within a plastic cartridge, referred to as the INSTI Membrane Unit. The membrane has been spotted with HIV-1 and HIV-2 antibody-binding recombinant proteins, which react with the HIV antibodies in the specimen to produce a distinct visual signal (a blue dot) on the membrane. The membrane also includes a procedural control to ensure the test has been performed correctly. The procedural control consists of a protein-A-treated spot capable of capturing human immunoglobulin G (IgG and/or IgM) antibodies normally present in blood and blood components. The antibodies then react with a proprietary chromatic agent to produce a visual signal on the membrane. Since IgG antibodies are present in blood (irrespective of HIV status), the control spot provides a visual signal when the test procedure has been followed correctly and the correct amount of sample applied.

If the control dot does not appear, the test is considered invalid. In the event of an invalid test, discard the test and retest with a new device. In the case of the test spot, recombinant HIV proteins embedded in the membrane capture HIV-specific antibodies if present in the specimen. Antibodies captured in the test spot react with a Protein A/indigo blue chromatic agent to produce a second visible dot on the membrane. The presence of both the control and test dots indicates a reactive HIV result which should be confirmed using a secondary test. The presence of the control dot and no test dot is a non-reactive result. The test device is designed to filter, absorb, and retain the test specimen and all the test reagents in such a manner as to limit leakage and exposure of personnel to potentially infectious materials.

The test is performed by adding the blood to the vial of Sample Diluent (Bottle 1), which lysed the red blood cells. This specimen/diluent solution is then poured into the well of the membrane unit. HIV-1 and HIV-2 antibodies, if present in the specimen, are captured by proteins on the filtration membrane. Color Developer (Bottle 2) is then added to the test device. The Color Developer reacts with the captured antibodies to generate a distinct blue dot at the location of the control spot and, in the case, where HIV-1/HIV-2 antibodies are present in the specimen, a blue dot also appears at the location of the test spot on the membrane.

In the final step, the Clarifying Solution (Bottle 3) is then added to the test device to decrease background color in order to make the control and test dots more distinct. The results are interpreted immediately after the Clarifying Solution is fully absorbed into the test device.

Upon addition of sample to the INSTI Solution 1, any blood cell material is lysed by the contents of the sample diluents and optimum sample dilution is achieved. When the contents of Solution 1 are subsequently poured into the INSTI test device, two immunoassay reactions can occur simultaneously and immediately: in the control spot, human IgG and/or IgM is captured by the protein A that is blotted onto the nitrocellulose membrane; in the test spot, antibodies to HIV-1 and/or HIV-2, if present, are captured by the recombinant antigens blotted onto the membrane.

The reactions are visualized after the addition of INSTI Solution 2 which contains a proprietary preparation of Protein A coupled to indigo dye, which attaches to any human IgG and/or IgM captured at the control and test spots. The Solution 3 removes any
background staining of the membrane surface, allowing for visual interpretation of results.”

**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>

**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
2. Instructions for use PN 90-1071
**INSTI HIV SELF TEST INSTRUCTIONS**

**Intended Use:**
For untrained lay users as a self test to detect HIV-1 and HIV-2 antibodies using a drop of human fingerstick blood

**Questions?**
+1-604-204-6784
www.insti.com

**PREPARATION**

- Wash hands with soap and dry.
- Clean finger with alcohol wipe.

1. **Open test device pouch.**
2. **Place test device on a flat surface.**
3. **Remove cap of Bottle 1. Place on flat surface.**

**STEP 1: COLLECT BLOOD**

- **Twist off tip and put aside.**
- **Rub finger until warm.**
- **Let 1 drop FALL into Bottle 1.**
- **Twist on cap of Bottle 1.**
- **Apply adhesive bandage.**

**STEP 2: TEST**

1. **Shake and pour all liquid.**
   - Wait until liquid disappears.
2. **Shake and pour all liquid.**
   - Wait until liquid disappears.
3. **Shake and pour all liquid.**
   - Wait until liquid disappears.

**STEP 3: READ RESULT**

- **NEGATIVE**
- **POSITIVE**
- **INVALID**

- **TEST AGAIN IN 3 MONTHS**
- **GO TO CLINIC FOR CONFIRMATORY TESTING**

- **INSTI® has a specificity of 99.5%.** This means a negative result will be correct 995 out of every 1000 tests.
- **INSTI® has a sensitivity of 99.8%.** This means a positive result will be correct 998 out of every 1000 tests.

**DISPOSAL**

- **Blood can transmit infectious diseases. Clean up spills.**
- **Dispose in accordance to local regulations.**
- **Shake 4 TIMES and POUR ALL.**
- **Shake 4 TIMES and POUR ALL.**
- **Shake 4 TIMES and POUR ALL.**

**INSIDE YOUR TEST KIT**

- Bottle 1, 2 & 3
- Test Device Pouch
- Lancet
- Bandage
- Alcohol Wipe

**INSIDE YOUR TEST KIT**

- 1
- 2
- 3

- **Do not use if the test device pouch is broken.**
- **Do not use if you:**
  - have a bleeding disorder
  - are on ART

**DISPOSAL**

- **Shake 4 TIMES and POUR ALL.**
- **Shake 4 TIMES and POUR ALL.**
- **Shake 4 TIMES and POUR ALL.**

**CAUTION**

- **Contains sodium azide.**
- **Harmful if swallowed.**
- **Sterilization using irradiation.**
- **Do not reuse.**

**Manufactured by bioLytical Laboratories Inc.**

- **For in vitro diagnostic use.**
- **Store at 15-30°C.**
- **1108 - 13351 Commerce Parkway, Richmond, BC V6V 2X7 Canada**
- **Phone: +1 604 204 6784**
- **Fax: +1 604 244 8399**
- **www.bioLytical.com**

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