WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: OraQuick HIV Self-Test
WHO reference number: PQDx 0159-055-01

OraQuick HIV Self-Test with product codes 5X4-1000, 5X4-1001 and 5X4-2001 manufactured in Thailand for OraSure Technologies, Inc., rest-of-world regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed 20 July 2017.

Summary of WHO prequalification assessment for OraQuick HIV 1/2 Self-Test

<table>
<thead>
<tr>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>PQ listing</td>
<td>8-Apr-2016 listed</td>
</tr>
<tr>
<td>Dossier review</td>
<td>26-Jan-2016 MR</td>
</tr>
<tr>
<td>Site inspection(s) of quality management system</td>
<td>3 - 5-Nov-2014 MR</td>
</tr>
<tr>
<td>Laboratory evaluation of performance and operational characteristics</td>
<td>28-Jan-2016 MR</td>
</tr>
</tbody>
</table>

MR: Meets requirements

OraSure Technologies, Inc submitted a change notification for their prequalified product OraQuick HIV 1/2 Rapid Antibody Test to introduce a new configuration with an intended use specific for HIV self-testing (OraQuick HIV 1/2 Self-Test). The new configuration was adapted from the corresponding professional use product (OraQuick HIV 1/2 Rapid Antibody Test) for which a WHO prequalification assessment has already taken place. Additional data was generated to meet particular requirements for self-testing as 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 Dossier assessment and laboratory evaluation for the OraQuick HIV 1/2 Self-Test were adapted from the professional use product, OraQuick HIV 1/2 Rapid Antibody Test prequalified in 2016. Please refer to the WHO Prequalification of Diagnostics Programme PUBLIC REPORT for OraQuick HIV 1/2 Rapid Antibody Test https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/

2 https://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf?sequence=1
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>Introduction of a new configuration with an intended use specific for HIV self-testing (OraQuick HIV Self-Test). The new configuration (OraQuick HIV Self-Test) was adapted from their professional use product (OraQuick HIV 1/2 Rapid Antibody Test) for which a WHO prequalification assessment had 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.</td>
<td>14-Jun-2016</td>
</tr>
<tr>
<td>3.0</td>
<td>Inclusion of a pharmacy distribution variant (5X4-2001) in addition to the existing community version (5X4-1000 and 5X4-1001)</td>
<td>8-May-2018</td>
</tr>
<tr>
<td>4.0</td>
<td>Inclusion of latest labelling and Correction of a typographical error.</td>
<td>20-Jun-2018</td>
</tr>
</tbody>
</table>
| 5.0                     | 1. Add 1 IFU to the labelling on the pouched device and implement the use of a blank inner and outer pouch to allow for customization of country specific information on the pouch. Added a statement to the Public Report for PQDx-0159-055-01 indicating that country specific variations are documented through a suffix “###” to the product code.  
2. Revision of the IFU from a double-sided single page to a single-sided single page. Added a limitation of the test in the IFU as follows “This product has not been evaluated for use in self-testing for individuals younger than 12 years of age. For children ages 2-11, testing must be performed by a trained health care worker”. Revision of the inner pouch to utilize ISO 15223 compliant symbols and addition of a disposal bag to both the community and pharmacy versions of the test kit. | 29-Nov-2019              |

3 http://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf;jsessionid=E2718EC36EF0D314EFE87E902244528E1?sequence=1
Intended use:

According to the claim of the manufacturer, “OraQuick HIV Self-Test is an in-vitro diagnostic medical device (IVD) that is used for self-testing of antibodies for HIV-1 and HIV-2 in oral fluid. This test is intended as an aid to detect antibodies to HIV-1 and HIV-2 from infected individuals”.

Assay description:

According to the claim of manufacturer, “OraQuick HIV-1/2 is a visually read, qualitative immunochromatographic test for the detection of IgG antibodies to HIV-1 and HIV-2. The flat pad that contacts the gums is treated with a mild surfactant, and no materials of viral origin are used in the manufacture of the test. One cannot become infected with HIV by taking this test. The device is placed into the subject’s mouth, so that the flat pad is between the cheek and the outer gums, then swabbed across the outer gum line. The device is then placed into a vial containing a premeasured amount of developer solution, and allowed to develop. Use only the stand provided to hold the developer vial. Fluid from the surface of the gums enters the device through the flat pad, then flows onto a test strip. As it migrates across the strip, it hydrates and mixes with a red-colored reagent (protein A bound to colloidal gold). IgG antibodies in the specimen bind to the reagent. If in turn the bound IgG antibody recognizes synthetic HIV-1 or HIV-2 antigen immobilized on the strip enclosed in the housing, a colored line forms in the ‘T’ (test) area of the result window. If not, no line forms there.

Further up the strip, the colored reagent encounters an immobilized biochemical that recognizes human antibodies. The line that forms in this ‘C’ area of the result window is the control line. It demonstrates assay validity, indicating that the oral fluid contains IgG, that the strip is functioning properly, and that fluid is migrating appropriately through the device”.

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4 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.
**Test kit contents:**

<table>
<thead>
<tr>
<th>OraQuick HIV Self-Test (community version)</th>
<th>OraQuick HIV Self-Test (pharmacy version)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>50 pouched kits (product code 5X4-1000)</strong></td>
<td><strong>110 pouched kits (product code 5X4-2001)</strong></td>
</tr>
<tr>
<td>Each pouched kit contains:</td>
<td>Each pouch kit contains the same pouched device configuration as the community version, except the entire pouched device (containing inner pouch, test stand, and an IFU) will be folded and placed into a carton.</td>
</tr>
<tr>
<td>• 1 divided pouch with</td>
<td></td>
</tr>
<tr>
<td>- a single use test device; and</td>
<td></td>
</tr>
<tr>
<td>- a desiccant; and</td>
<td></td>
</tr>
<tr>
<td>- a developer solution vial</td>
<td></td>
</tr>
<tr>
<td>containing 1ml of phosphate buffer</td>
<td></td>
</tr>
<tr>
<td>saline solution containing polymers</td>
<td></td>
</tr>
<tr>
<td>and an antimicrobial agent</td>
<td></td>
</tr>
<tr>
<td>• 1 test stand</td>
<td></td>
</tr>
<tr>
<td>• 1 instructions for use</td>
<td></td>
</tr>
<tr>
<td>• 1 disposal bag</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:**
The inner pouch’s product code is REF 5X4-0004 and suffix XXX is the designation for different versions of the IFU that are country specific due to required languages.

The outer pouch of the product has the suffix (i.e. numbers .001, .002, …). The inner pouch does not have a suffix because that is not country specific.

Product codes are listed as 5x4-1000, 5x4-1001 and 5x4-2001 are for the entire kit boxes, i.e. different sizes, configurations (pharmacy pack or community pack).

**Items required but not provided:**

<table>
<thead>
<tr>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clock, watch or timing device</td>
</tr>
</tbody>
</table>

**Storage:**

- Store and perform this test in a cool area.
- DO NOT use this test if it has been stored outside the acceptable temperature of 2 to 30 °C (36 °- 86 °F).
- This test should be performed at temperatures in the range of 15 to 37 °C (59 °- 99 °F).
**Shelf-life upon manufacture:**
30 months.

**Warnings:**
- Refer to current version of manufacturer’s instructions for use.

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

**Commitments:**
Final report of shipping stability to demonstrate the acceptable performance of the unit box and the device after shipping stressors, report due 31 March 2018. The commitment was closed.
Labelling

1. Labels

2. Instructions for use
I. Community version

1. Device Label 3001-3035 rev 03/17

![Device Label Image]

2. Developer Vial Label 3001-3034 rev 03/17

![Developer Vial Label Image]
3. Inner Pouch 3001-3036 revision 10/19
4. Outer Pouch 3001-2824, revision 05/18
5. 50 Count Shipper Box 3001-3039 rev 07/17

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HIV SELF-TEST

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6. 250 Count Shipper 3001-3040 rev 07/17
II. Pharmacy version

1. Outer carton 3001-3042, revision 05/19
2. Count shipper box (item # 3001-3060-70 rev. 08/17)
7. Instructions for use

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5 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
What is this test for?
OraQuick® is an Oral HIV Self-Test. HIV cannot be transmitted by saliva. This test works by detecting your body's natural antibodies that help you fight infection. Use only as an oral test. Use this test only as described in the instructions for use.

When should I use this test?
You should use this test if you want to know your HIV status. If you are infected by HIV, OraQuick® will detect antibodies and your test will be POSITIVE. If you have not been infected by HIV, your test will be NEGATIVE. If you have been recently infected with the HIV virus, your body may not be making antibodies yet. If you are using this test earlier than 3 months since a risk event and your test is NEGATIVE, you should test again 3 months after the risk event. A risk event is defined by any of the list of activities below:

• Sex (vaginal, oral or anal) with multiple sex partners.
• Sex with someone who is HIV positive or whose HIV status you don’t know.
• Sex between a man and another man.
• Using illegal injected drugs or steroids.
• Shared needles or syringes.
• Exchanged sex for money.
• Having been diagnosed or treated for hepatitis, tuberculosis or a sexually transmitted disease like syphilis.

You can also use this test:
✓ If you are pregnant, test anytime.

When should I NOT use this test?
• Most people feel a little bit nervous when taking an HIV test. If you feel very nervous about taking the test, you may want to wait to take it, or get tested at a local clinic or testing center.
• If the box seal is broken or if any of the package contents are missing, broken, or open.
• If you are HIV positive.
• If today is after the use by date on the side of the box.
• If you are age 11 or younger.

For more information visit:
www.oraquickhivselftest.com
**HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT**

1. **Open the kit** and remove the test device and tear open the pouch containing the test device.

2. **Preservative** is not needed for the test.

3. **Do NOT** touch the flat pad with your fingers. **Do NOT** wet or swab the preservative.

4. **Put in** the eye dropper, tear open the pouch containing the tube. **DO NOT** pour out the liquid. **DO NOT** drink.

5. **Remove the cap.**

6. **Tear open pouch containing the test device and remove.** **DO NOT** touch the flat pad with your fingers. **DO NOT** wet or swab the preservative.

7. **Tear open pouch containing the tube.**

8. **Press the Flat Pad firmly against your gum and swab it along your upper gum once (fig. 1) and your lower gum once (fig. 2).**

9. **Put the flat pad all the way into the tube until it touches the bottom.**

10. **Put the test stick, put the cap on the test tube, place in the disposal bag provided and throw away all contents in the normal trash.**

11. **Leave it there for 20 MINUTES before reading the results.** **DO NOT** read the result after 40 minutes.

**INTERPRETING RESULTS**

**HIV POSITIVE RESULT**

Two complete lines, even if the line is faint, means you may be HIV POSITIVE and you need to seek additional testing by a trained professional to confirm an HIV diagnosis.

**HIV NEGATIVE RESULT IF READ BEFORE 20 MINUTES, RESULT MAY NOT BE CORRECT**

**INVALID RESULT**

If there is no line next to the “C” (even when there is a line next to the “T”), the test line or control line are not complete, all the way across the window, or a red background makes it impossible to read the test, the test is not working and should be repeated. You will need to obtain another test. 1.8% of study subjects (16 out of 900) failed to obtain a test result.

**NOT SURE OF RESULT**

You do not know your result or you are unsure of your result. Visit your nearest HIV Testing Centre or Health Facility to test again.

**PRODUCT INFORMATION**

**INSTRUCTIONS FOR USE**

The OraQuick® HIV Self-Test is an in vitro diagnostic medical device (IVD) that is used for self-testing of antibodies for HIV-1 and HIV-2 in oral fluid. This test is intended as an aid to detect antibodies to HIV-1 and HIV-2 in infected individuals. You must follow the test directions carefully to get an accurate result.

**WARNINGS AND PRECAUTIONS**

- **Do NOT** use the test if you are HIV positive.
- **Do NOT** use the test if it has been exposed to household cleaning products (i.e. bleach).
- **Do NOT** use the test if it is after the “Use By” on the outside of the pouch, do not use this test.
- **Do NOT** use the test if any of the package contents are missing, broken, or open.
- **If today is after the “Use By” on the outside of the pouch, do not use this test.
- **Do NOT** eat or drink for at least 15 minutes before you start the test or use mouth cleaning products 30 minutes before you start the test.

**LIMITATIONS OF THE TEST**

- Oral bleeding may result in an invalid result. If the test result is invalid, visit your nearest testing center or healthcare facility.
- The OraQuick® HIV Self-Test may not detect HIV infections that have occurred within the last 3 months.
- For a positive result, the intensity of the test line does not necessarily equal the amount of antibody in the specimen.
- This product has not been evaluated for use in self-testing for individuals younger than 12 years of age. For children ages 3-11, testing must be performed by a trained health care worker.

**INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS**

- The OraQuick® HIV Self-Test may not detect HIV infections that have occurred within the last 3 months.
- Oral bleeding may result in an invalid result. If the test result is invalid, visit your nearest testing center or healthcare facility.
- The OraQuick® HIV Self-Test may not detect HIV infections that have occurred within the last 3 months.
- For a positive result, the intensity of the test line does not necessarily equal the amount of antibody in the specimen.
- This product has not been evaluated for use in self-testing for individuals younger than 12 years of age. For children ages 3-11, testing must be performed by a trained health care worker.

**EXPLANATION OF SYMBOLS**

- **X1** Do Not Use
- **X2** HIV Diagnostic Medical Device
- **X3** Date of Expiration
- **X4** Date of Manufacturing
- **X5** Use By
- **X6** Temperature Limitation
- **X7** Caution, Consult Accompanying Documents
- **X8** Batch Code
- **X9** Catalog Number
- **X10** Exp
- **X11** Age Restriction
- **X12** Do Not Reuse
- **X13** In Vitro
- **X14** Do Not Drink
- **X15** Do Not Eat
PRODUCT INFORMATION

HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT

INSTRUCTIONS FOR USE

The OraQuick® HIV Self-Test is an in vitro medical device (IVD) that is used for self-testing of antibodies for HIV-1 and HIV-2 in oral fluid. This test is intended as an aid to detect antibodies to HIV-1 and HIV-2 from infected individuals. You must follow the test directions carefully to get an accurate result.

For Outside USA Use Only • In Vitro Diagnostic Use • Do Not Reuse

WARNING: If you are on HIV treatment you may get a false result. Clinical data has not been collected to demonstrate the performance of OraQuick® HIV Self-Test in individuals that are undergoing PREP.

1. YOU WILL NEED A WAY TO TIME THE TEST

YOU DO NOT NEED A WAY TO TIME THE TEST

Your test kit contains two pouches.

• Tear open the pouch containing the test device and remove. DO NOT touch the flat pad with your fingers. DO NOT wet or swaddle the preservation.

2. HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT

• DO NOT use the test if it has been exposed to household cleaning products (i.e., bleach).
• If today is after the 'Use By' on the outside of the pouch, do not use this test.
• DO NOT use the test if you are HIV positive.

3. DISPOSAL

• DO NOT EAT.
• DO NOT MAKE CONTACT WITH THE ELISA WIND CHIMES.

4. IF READ BEFORE 20 MINUTES, RESULT MAY NOT BE CORRECT

• DO NOT pour out the liquid. DO NOT drink.
• Slide the tube into the test stand.

5. INTERPRETING RESULTS

READ TEST RESULTS IN A WELL-LIT AREA

Visit your nearest HIV Testing Centre or Health Facility to test again.

6. HIV POSITIVE RESULT

Visit your nearest HIV Testing Centre or Health Facility to test again.

• Ten complete lines, even if the line is faint, means you may be HIV POSITIVE and you need to seek additional testing by a trained professional to confirm an HIV diagnosis.

• 99.4% of people (152 out of 153) correctly reported their result as positive. This means that 1 out of 103 people infected with HIV reported a negative test result. This is called a false negative.

• DO NOT use any of the package contents are missing, broken, or open.

7. HIV NEGATIVE RESULT

Visit your nearest HIV Testing Centre or Health Facility to test again.

• ONE LINE next to the "C" and NO line next to the "T", your result is HIV NEGATIVE.

• 99.0% of people (717/724) correctly reported their result as negative. This means that 7 out of 724 people not infected with HIV reported a positive test result. This is called a false positive.

• 1.8% of study subjects (16 out of 900) failed to obtain a test result.

8. INVALID RESULT

If the test did not work properly. Visit your nearest HIV Testing Centre or Health Facility to test again.

9. NOT SURE OF RESULT

You do not know your result or you are unsure of your result. Visit your nearest HIV Testing Centre or Health Facility to test again.

• DO NOT eat or drink for at least 15 minutes before you start the test or use mouth cleaning products 30 minutes before you start the test.

• Remove dental products such as dentures or any other products that cover your gums prior to the oral fluid collection.

• It is recommended that users observe a 15-minute wait period after food and drink and a 30-minute wait period after using oral care products.

• Clinical data has not been collected to demonstrate the performance of OraQuick® HIV Self-Test in individuals that are undergoing PREP.

10. WARNINGS AND PRECAUTIONS

• DO NOT use the test if it has been exposed to household cleaning products (i.e., bleach).
• If today is after the 'Use By' on the outside of the pouch, do not use this test.
• DO NOT use the test if you are HIV positive.

11. EXPLANATION OF SYMBOLS

• Do Not Use
• In Vitro Medical Device
• Date of Expiration
• Warnings
• Date of Manufacturing

Interfering Substances and Unrelated Medical Conditions

If you are HIV, HCV or HTLV (I/II) positive, you may get a false result. This is recommended that users observe a 15-minute wait period after food and drink and a 30-minute wait period after using oral care products.