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.###1, 5X4-1001.###1, 5X4-2001.###1, 5X4-7000.050, 5X4-7000.250, 5X4-7000.200, and 5X4-0004.### 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 Self-Test

<table>
<thead>
<tr>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>PQ listing</td>
<td>8 April 2016 listed</td>
</tr>
<tr>
<td>Dossier review</td>
<td>26 January 2016 MR</td>
</tr>
<tr>
<td>Site inspection(s) of quality management system</td>
<td>3 - 5 November 2014 MR</td>
</tr>
<tr>
<td>Laboratory evaluation of performance and operational characteristics</td>
<td>28 January 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 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 Country specific variations are documented through a suffix “###” to the product code.
2 Dossier assessment and laboratory evaluation for the OraQuick HIV 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/
3 https://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf;jsessionid=153ABC9D88E7623A1AD1DF946A22B4C8?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(^4).</td>
<td>14 June 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 June 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 November 2019         |
| 6.0                     | Correction of product codes to reflect country specific variations documented through a suffix “####” to the product code on the outer packaging (i.e. 5X4-1001.001, .002, ...). Change on product labelling due to minor revisions.                                                                                                                                                  | 17 December 2021         |

\(^4\) http://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf?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 Self-Test 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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5 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><strong>OraQuick HIV Self-Test (community version)</strong></th>
<th><strong>OraQuick HIV Self-Test (pharmacy version)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product code 5X4-1000.### - 50 pouched kits</strong></td>
<td><strong>Product code 5X4-1001.### - 250 pouched kits</strong></td>
</tr>
<tr>
<td>Each pouched kit (5X4-0004.xx) contains:</td>
<td>Each pouched kit (5X4-0004.xx) contains:</td>
</tr>
<tr>
<td>• 1 divided pouch with</td>
<td>• 1 divided pouch with</td>
</tr>
<tr>
<td>- a single use test device; and</td>
<td>- a single use test device; and</td>
</tr>
<tr>
<td>- a desiccant; and</td>
<td>- a desiccant; and</td>
</tr>
<tr>
<td>- a developer solution vial</td>
<td>- a developer solution vial</td>
</tr>
<tr>
<td>containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent</td>
<td>containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent</td>
</tr>
<tr>
<td>• 1 test stand</td>
<td>• 1 test stand</td>
</tr>
<tr>
<td>• 1 instructions for use</td>
<td>• 1 instructions for use (IFU)</td>
</tr>
<tr>
<td>• 1 disposal bag</td>
<td>• 1 disposal bag</td>
</tr>
<tr>
<td><strong>50 pouched kits (product code 5X4-7000.050)</strong></td>
<td><strong>250 pouched kits (product code 5X4-7000.250)</strong></td>
</tr>
<tr>
<td>Each pouched kit (5X4-7000) contains:</td>
<td>Each pouched kit (5X4-7000) contains:</td>
</tr>
<tr>
<td>• 1 divided pouch with</td>
<td>• 1 divided pouch with</td>
</tr>
<tr>
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</tr>
<tr>
<td>• 1 disposal bag</td>
<td>• 1 disposal bag</td>
</tr>
</tbody>
</table>

### OraQuick HIV Self-Test (pharmacy version)

<table>
<thead>
<tr>
<th><strong>Product code 5X4-20001.### - 200 boxed kits (5X4-2001U.###)</strong></th>
<th><strong>Product code 5X4-7000.200) - 200 Boxed kits (5X4-7000P)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Each boxed kit (5X4-2001U.###) contains:</td>
<td>Each boxed kit (5X4-7000P) contains:</td>
</tr>
<tr>
<td>• 1 divided pouch with</td>
<td>• 1 divided pouch with</td>
</tr>
<tr>
<td>- a single use test device; and</td>
<td>- a single use test device; and</td>
</tr>
<tr>
<td>- a desiccant; and</td>
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<td>- a developer solution vial</td>
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<td>containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent</td>
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<td>• 1 test stand</td>
<td>• 1 test stand</td>
</tr>
<tr>
<td>• 1 instructions for use</td>
<td>• 1 instructions for use</td>
</tr>
</tbody>
</table>
Each kit contains the same pouched device configuration as the community version, except the contents are contained in a carton.

### OraQuaick HIV-Self-Test (individual unit product code 5x4-0004.###)

- 1 divided pouch with
  - a single use test device; and
  - a desiccant; and
  - a developer solution vial
  containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent
- 1 test stand
- 1 instructions for use
- 1 disposal bag

**NOTE:**

Country specific variations are documented through a suffix “###” to the product code on the outer packaging (i.e. 5X4-1001.001, .002, ...). Therefore, product codes 5X4-1000.###, 5X4-1001.### and 5X4-2001.### are prequalified product codes. The country specific product code relates to the language of the IFU provided within the product.

The single pouch product code REF 5X4-0004.### and the single box product code REF 5X4-2001U.###, where the suffix .### is the country specific/language designation, are prequalified products.

**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 (IFU).

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

2. Developer Vial Label 3001-3034 rev 03/17
4. Outer Pouch 3001-2824, revision 01/21
or 3001-3431 revision 11/20
or 3001-3662, revision 02/22
ORAQUICK® HIV SELF-TEST

REFER TO TESTING DIRECTIONS INSIDE PACK

CONTENTS:
1. Instructions for Use
1. Test Device
1. Preservative
1. Developer Mix
1. Test Stand
1. Disposal Bag

IVD
ONE TIME USE
NOT FOR REUSE

STORAGE:
30°C
STORAGE IN A COOL PLACE

MANUFACTURED BY:
OraSure Technologies, Inc.
159 East Red Hill Blvd., Bethlehem, PA 18015-1854
www.orsure.com

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Rev 1.01 11/12/2010
อวัยวิสูตร เซลฟ์ เหสต์

ผลลัพธ์:

ผลลัพธ์ที่ได้จะมีการเปลี่ยนแปลงตามวัสดุที่ใช้ในการตรวจสอบ ซึ่งผลลัพธ์จะถูกแสดงในรูปแบบมุกคละ

เฉพาะสภาวะที่เกิดขึ้นกับสารก่อภัยพื้นฐานของตัวเชื้อเมื่อคู่ลงหลีก

หมายเหตุ:

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5. 50 Count Shipper Box 3001-3039 revision 01/21
   Or 3001-3460 revision 04/21
   Or 3001-3658 revision 02/22
   Or 3001-3655 revision 05/20
   Or 3001-3394 revision 05/20
6. 250 Count Shipper 3001-3040 revision 01/21
Or 3001-3461 revision 04/21
Or 3001-3659 revision 02/22
Or 3001-3395 revision 05/20
Or 3001-3656 revision 05/20
II. Pharmacy version

1. Outer carton 3001-3179 revision 01/19
   Or 3001-3458 revision 09/20C
   Or 3001-3399 revision 05/20
2. 200 Count shipper box 3001-3177 revision 10/21
   Or 3001-3657 revision 05/20
7. Instructions for use

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6 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
HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT

1. Open pouch containing the test device and remove. DO NOT touch the flat pad with your fingers. DO NOT eat or swallow the preservative.

2. 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).

3. Remove the cap.

4. Tear open the pouch containing the test tube.

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

6. DO NOT pour out the liquid. DO NOT drink.

7. Slide the tube into the stand.

INTERPRETING RESULTS

Read test results in a well-lit area

HIV POSITIVE RESULT

Two complete lines, even if the line is faint, means you are HIV POSITIVE and you should 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 100 people infected with HIV reported a negative test result. This is called a false negative.

HIV NEGATIVE RESULT

IF READ BEFORE 20 MINUTES, RESULT MAY NOT BE CORRECT

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.

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 is 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

REF: 5X4-100X, 5X4-1001, 5X4-2001

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 if any of the package contents are missing, broken, or open.
• DO NOT use if 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.
• It is recommended that users cleanse a 15 minute wait period after food and drink and a 30 minute wait period after using oral care products.

LIMITATIONS OF THE TEST

Oral bleeding may result in an invalid result. If the test result is invalid, visit your nearest testing centre or healthcare facility.

The OraSure HIV Self Test may not detect HIV infections that have occurred within the last 3 months.

If you are HBV, HCV or HTLV (I/II) positive, you may get a false result.

DOSE ADMINISTRATION

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.

DISPOSE

Remove 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.

EXPLANATION OF SYMBOLS

REF: Reference number

AB: Age Restriction

DD: Date of Disposal

ET: Expiration Date

LC: Lot Code

MD: Manufacturer Date

MT: Manufacture Date

ND: Not Determined

OUI: Oui

PO: Pour out

SD: Shelf Life Date

W: Wipe

WWW: www.oraquick.com