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 and 5X4-1001 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.

Intended use:
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:
OraQuick® HIV Self-Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid. OraQuick® HIV Self-Test is intended for use by lay users as a self-test to aid in the diagnosis of infection with HIV-1 and HIV-2. The device is placed into the 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 tube containing a premeasured amount of solution. Fluid from the surface of the gums enters the device through the flat pad, then flows onto a test strip. As it flows across the strip, a colored line forms in the ‘T’ (test) area of the result window if HIV antibodies are detected. If no HIV antibodies are detected, no line forms there. If the test is performed correctly, a line forms in the ‘C’ area of the result window.

Test kit contents:

<table>
<thead>
<tr>
<th>50 pouched kits (product code 5X4-1000)</th>
<th>250 pouched kits (product code 5X4-1001)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each pouched kit contains:</td>
<td>Each pouched kit 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</td>
</tr>
</tbody>
</table>
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:
The test kit should be stored at 2 to 30 °C.
- 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°-30° C (36°-86° F).
- This test should be performed at temperatures in the range of 15°-37° C (59°-99° F).

Shelf-life upon manufacture:
30 months.

Warnings:
- Most people feel a little bit nervous when taking an HIV test. But, if you feel very nervous about taking the test, you may want to wait until you are calmer to take it, or get tested by your doctor or local clinic.
- DO NOT use the test if you are HIV positive.
- Use with oral fluid only. The test is not for use with blood, serum, breast milk, plasma, semen, urine, vaginal fluid or sweat.
- DO NOT eat or drink for at least 15 minutes before starting the test.
- DO NOT use mouth cleaning products (such as mouthwash) 30 minutes before starting the test.
- Remove dental products such as dentures or any other products that cover your gums prior to the oral fluid collection.
- If the tamper-evident seal is broken or if any of the package contents are missing, broken, or open, do not use this test.
- If today is after the ‘Use By’ on the outside of the pouch, do not use this test.
- Individuals must have adequate lighting to read a test result. If two lines are present at areas marked “T” and “C” on the Test Device at any visible intensity, the test result is interpreted as positive.
- DO NOT open any of the pouches until you are ready to begin your test.
- DO NOT use the test if it has been exposed to household cleaning products (i.e. bleach).
- If you have participated in a HIV vaccine clinical trial, you may get a positive result using this test, but it may not mean that you are infected with HIV. You should seek follow-up with your health facility.

Limitations:
- The OraQuick® HIV Self-Test kit Instructions for Use must be followed carefully to get an accurate result.
- If you are on HIV treatment (ARVs) you may get a false result.
- If you are HBV, HCV or HTLV (I/II) positive, you may get a false result.
• Oral bleeding may result in an invalid result. If the test result is invalid, visit your nearest testing center or healthcare facility.
• Clinical data has not been collected to demonstrate the performance of OraQuick® HIV Self-Test in individuals that are undergoing PrEP.
• 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.
• Positive results should be verified using another test performed by a trained professional to confirm an HIV diagnosis.
Summary of WHO prequalification change assessment for OraQuick HIV Self-Test

<table>
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<tr>
<th>Date</th>
<th>Outcome</th>
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<td>listed</td>
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<tr>
<td>20 July 2017</td>
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MR: Meets requirements

Change notification

In 2016, OraSure Technologies, Inc., submitted a change notification to their existing product (OraQuick HIV 1/2 Rapid Antibody Test) which was to introduce a new configuration with an intended use specific for HIV self-testing (OraQuick HIV Self-Test). It was stated that new configuration (OraQuick HIV Self-Test) has been adapted from their professional use product (OraQuick HIV 1/2 Rapid Antibody Test) for which WHO prequalification assessment had already taken place. Additional data was generated to support meeting the WHO technical specification series for HIV-1/2 rapid diagnostic tests.

The change notification was assessed and product was found to meet WHO prequalification requirements.

Commitments:
1. Further studies to support analytical specificity, report due October 2017.

Summary of WHO prequalification assessment for OraQuick HIV 1/2 Rapid Antibody Test

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</tr>
<tr>
<td>28 January 2016</td>
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MR: Meets requirements
Labelling

1. Labels
2. Instructions for use
Developer Vial Label 3001-3034 rev 03/17

Inner Pouch 3001-3036 rev. 04/17 with JIT
Instructions for use/Directions for use 3001-3031 rev 07/17

**HOW TO USE THE ORAQUICK HIV SELF-TEST KIT**

1. **You will need a way to time the test.**
2. Put solution tube and test stand into test stand for use.
3. Your test kit contains test papers. Test kit. Must have test papers containing the liquid.
4. Mix the test kit thoroughly against your hands and open the upper right upper paper with your hands. Mix the test kit thoroughly against your hands and open the upper right upper paper.
5. Mix the test kit thoroughly against your hands and open the upper right upper paper.
6. Pull the test kit out of the pack.
7. Drop the tube into the round.
8. LEAVE IT THERE FOR 20 MINUTES before reading the results.
9. Read the result after 20 minutes.

**INTERPRETING RESULTS**

**HIV POSITIVE RESULT**

You have HIV. Consider informing your doctor and you need to seek medical testing.

**HIV NEGATIVE RESULT**

If read before 20 minutes, result may not be correct.

**INVALID RESULT**

The test was not completed correctly.

**NOT SURE OF RESULT**

You do not know your result if you are unsure of your result.

**DISPOSE**

Remove the test kit, put the cap on the test tube and throw away the container in the normal trash.
PRODUCT INFORMATION

INTENDED USE

The OnQuickHIV Self-Test is an in-vitro diagnostic medical device (IVD) that is used for self-testing of antibodies to 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.

SUMMARY OF THE TEST

The OnQuickHIV Self-Test is a single-use, qualitative immunassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid. The OnQuickHIV Self-Test is intended for use by lay users as a self test to aid in the diagnosis of infection with HIV-1 and HIV-2. The device is placed into the mouth, so that the test results between the test and control areas of the test strip are visible. The device is then placed into a bottle containing a preservative amount of solution. Fluid from the surface of the gum enters the device through the blister pack, then flows into a test strip. As it flows across the strip, a colored line forms in the test area. The test result is interpreted as positive or negative by observing the presence or absence of a colored line in the test area. This is called the control line.

TEST PERFORMANCE

In a clinical study, 305 people whose HIV status was known were given the OnQuickHIV Self-Test to use. The results were compared to a 4th generation laboratory test. The laboratory test results show that a total of 20 people tested HIV positive and 285 people tested HIV negative. The comparison of results was as follows:

• 103% of people (16 out of 16) correctly reported their result as negative. This means that 16 people infected with HIV were accurately reported as HIV negative.
• 101% of people (27 out of 27) correctly reported their result as positive. This means that 27 people not infected with HIV were accurately reported as HIV positive.
• In addition, only 7% of study subjects (3 out of 41) failed to obtain a test result.

KIT CONTENTS

• One pouch pack containing:
  Dried Pouch (DX-0101) with single use Test Device, Preservative and a Developer Solution Vial
  Test Strip
  Instructions for Use

Materials required but not provided: Clock, watch, or timing device.

WARNINGS AND PRECAUTIONS

• Most people feel a little bit nervous when taking an HIV test. Yet, if you feel nervous about taking the test, you may want to wait until you are calmer to take it, or try tested by your doctor or local clinic.
• DO NOT use the test if you are HIV positive.
• Use with oral fluid only. The test is not for use with blood, semen, breast milk, plasma, semen, urine, vaginal fluid or sweat.
• DO NOT eat or drink for at least 15 minutes before starting the test.
• DO NOT use mouth cleaning products (such as mouthwash) 30 minutes before starting the test.
• Remove dental products such as dentures or any other products that cover your gums prior to the fluid collection.
• If the tamper-evident seal is broken or if any of the package contents are missing, broken, or open, do not use the test.
• If the test is stored in the silica gel pouch, do not use this test.
• Individuals must have adequate lighting to read a test result. If two lines are present at areas marked “C” and “T” on the TestDevice at any visible intensity, the test result is interpreted as positive.
• DO NOT open any of the pouches until you are ready to begin your test.
• DO NOT use the test if it has been exposed to household cleaning products (i.e. bleach).
• If you have participated in a HIV vaccine clinical trial, you may get a positive result using this test, but it may not mean that you are infected with HIV. You should seek follow-up with your health facility.

-20°C STORAGE

• Store and perform this test in a cool area.
• DO NOT use this test if it has been stored above the acceptable temperature of +1°C to +8°C (35°F to 46°F).
• This test should be performed at temperatures in the range of 15°C to +37°C (59°F to 99°F).

LIMITATIONS OF THE TEST

• The OnQuickHIV Self-Test kit instructions for use must be followed carefully to get an accurate result.
• If you are HIV treatment (HAART) you may get a false result.
• If you are using a drug that may affect your antibody results, you may get a false result.
• Oral bleeding may result in an invalid result. If the test result is invalid, visit your nearest testing center or healthcare facility.
• Clinical data has not been collected to demonstrate the performance of OnQuickHIV Self-Test kit in individuals that are undergoing HAART.
• The OnQuickHIV Self-Test kit 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.
• Positive results should be verified using another test performed by a trained professional to confirm an HIV diagnosis.

QUESTIONS & ANSWERS

1. What does the test do?
OnQuickHIV Self-Test is an in-vitro diagnostic self-test for HIV-1 and HIV-2 in oral fluid. The test works by detecting your body's natural antibodies that help you fight infection. A positive result is preliminary and additional testing at a health facility is required to confirm the result.

2. What is a 'risk event' for HIV?
A risk event is defined by any of the below activities:

• Sex (vaginal, anal or oral) 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.
• Exchanging sex for money.
• Having been diagnosed or treated for hepatitis, tuberculosis or a sexually transmitted disease like syphilis.

3. How soon after a risk event can I test?
You can test any time after you are using this test earlier than 3 months since a risk event and your test to negative, your result may not be accurate. You should test again 3 months after the risk event to be sure. You can also be tested at a health facility.

4. Why should I use this test right after a risk event?
When you have been infected with the HIV virus, your body tries to fight the HIV virus by producing natural antibodies. These antibodies can be found in your oral fluid. It takes your body up to 3 months to make these antibodies at levels that can be detected by this test.
5. How accurate is the test?
In a clinical study, 400 people who were unaware of their HIV status were given the OraSure HIV Self-Test to use. The results were compared to a 4th generation laboratory test. The laboratory results show that a total of 196 people were HIV positive and 204 people were HIV negative. The comparison of results was as follows:
- 100% of people (196 out of 196) correctly reported their result as positive.
- 99.5% of people (202 out of 204) correctly reported their result as negative. This means that 2 out of 304 people not infected with HIV reported a positive test result. This is called a false positive.
- 100% of people (204 out of 204) correctly reported their result as negative.
- 100% of people (204 out of 204) correctly reported their result as negative. This means that 2 out of 304 people infected with HIV reported a negative test result. This is called a false negative.

6. Can I get HIV by using this test?
This test does not contain any materials or HIV virus that can cause HIV infection.

7. How often should someone test for HIV?
If you have never been tested for HIV, you should be tested at least once. If you do things (risk events) that can result in HIV infection, you should repeat tests every year (World Health Organization recommendation).

8. What happens when you test positive?
A positive test result means that the test has detected HIV. It is important to obtain a confirmatory test because this test has a false positive rate of 1%. To confirm a positive test result, you must undergo a confirmatory test. This test is usually an HIV antibody test.

9. What if I test negative?
If you have not participated in risk events in the past 3 months, and you follow the directions for use carefully, then you are most likely HIV negative. If you do participate in risk events in the past 3 months, you should be referred to a healthcare provider for further testing.

10. What happens when you test negative?
A negative test result means that the test did not detect HIV. It is important to obtain a confirmatory test because this test has a false negative rate of 1%. To confirm a negative test result, you must undergo a confirmatory test. This test is usually an HIV antibody test.

11. What should I do if I get a positive result?
You should follow up with a healthcare provider to get additional testing to confirm the result. At that time you can talk with a local clinic, doctor, or healthcare professional about what steps to take based on your test result.

12. Can I get wrong results?
There are no known false positive or false negative results with this test.

13. Can I get a false positive result with this test?
A false positive result means that the test has detected HIV. It is important to obtain a confirmatory test because this test has a false positive rate of 1%. To confirm a positive test result, you must undergo a confirmatory test. This test is usually an HIV antibody test.

14. Where can I get additional help or care for HIV?
You can get additional help through a local clinic, doctor, or healthcare professional.

15. Can I use this test to prevent HIV (PrEP)?
If you are taking oral PrEP for HIV, you may get a false result.

16. What is the recommended time to wait after a test?
If your test is not a positive test, you can take another test after 24 hours. If you are positive, you should seek medical attention immediately.

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS
As part of the test kit instructions, information was collected from participants regarding concurrent diseases or medical conditions, oral medications, non-HIV viral infections, and other factors (e.g., use of tobacco products, methamphetamine, over-the-counter medications, dental treatments, and the effects of alcohol). In a separate study of 40 individuals, consumption of alcohol, smoking, or both were tested. The test results were found to be accurate in all cases.

EXPLANATION OF SYMBOLS

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>LTC1</td>
<td>Batch Code</td>
</tr>
<tr>
<td>PEF</td>
<td>Catalog Number</td>
</tr>
<tr>
<td>EXP</td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td>BVD</td>
<td>Do Not Use</td>
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<tr>
<td>USE</td>
<td>In Vitro Diagnostic Medical Device</td>
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<td>Consult Accompanying Documents</td>
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<td>EXP</td>
<td>Date of Expiration</td>
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<td>DOM</td>
<td>Date of Manufacturing</td>
</tr>
</tbody>
</table>

Manufactured in Thailand by
OraSure Technologies, Inc.
235 East 9th Street, Bethlehem, PA 18015 USA
(610) 794-4261 FAX (610) 794-1620
www.OraSure.com
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