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:

50 pouched kits (product code 5X4-1000)	**250 pouched kits (product code 5X4-1001)**
Each pouched kit contains: • **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**	Each pouched kit contains: • **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**

Items required but not provided:

Item
Clock, watch or timing device

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

	Date	Outcome
PQ amended for OraQuick HIV Self-Test	20 July 2017	listed
Labelling accepted	20 July 2017	MR
Change reviewed	20 July 2017	MR

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.
2. Final report of usability studies, report due October 2017.

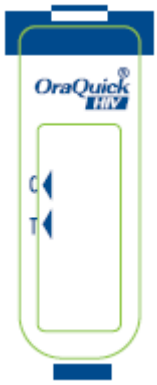
Summary of WHO prequalification assessment for OraQuick HIV 1/2 Rapid Antibody Test

	Date	Outcome
PQ amended	14 June 2016 2 February 2017	listed
PQ listing	8 April 2016	listed
Dossier review	26 January 2016	MR
Site inspection(s) of quality management system	8 January 2016	MR
Laboratory evaluation of performance and operational characteristics	28 January 2016	MR

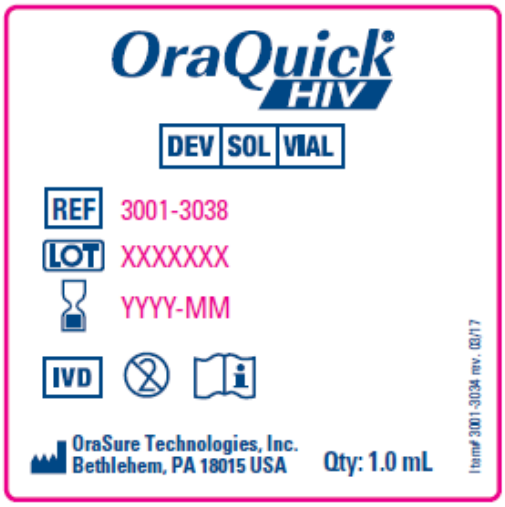
MR: Meets requirements

Labelling

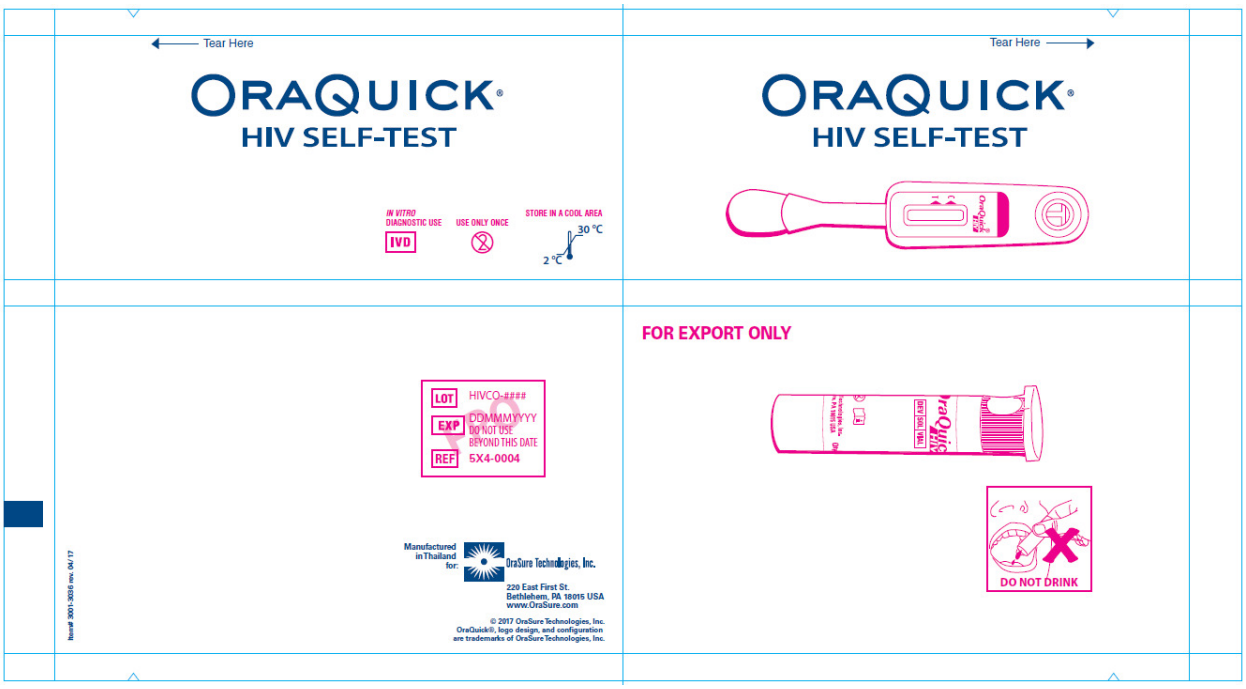
1. **Labels**
2. **Instructions for use**



Developer Vial Label 3001-3034 rev 03/17

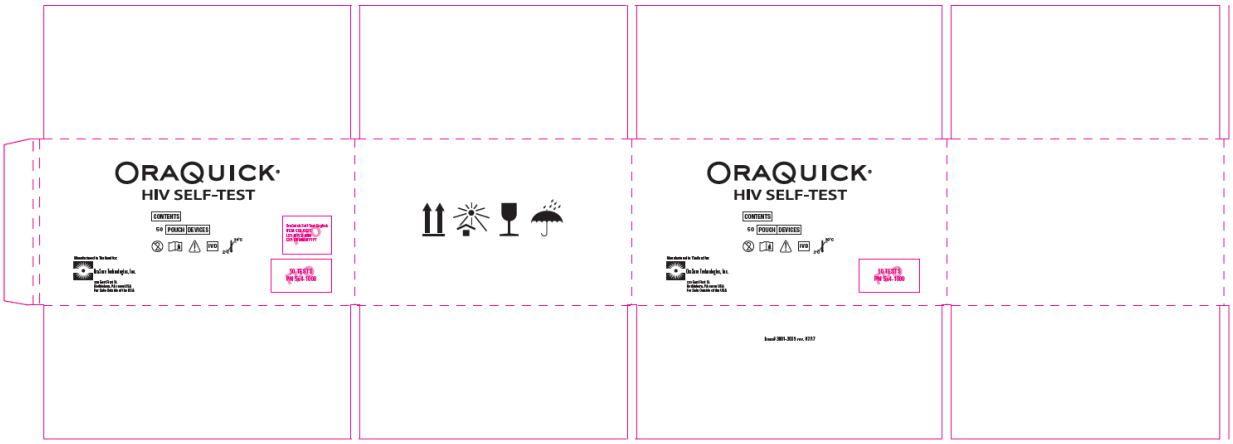


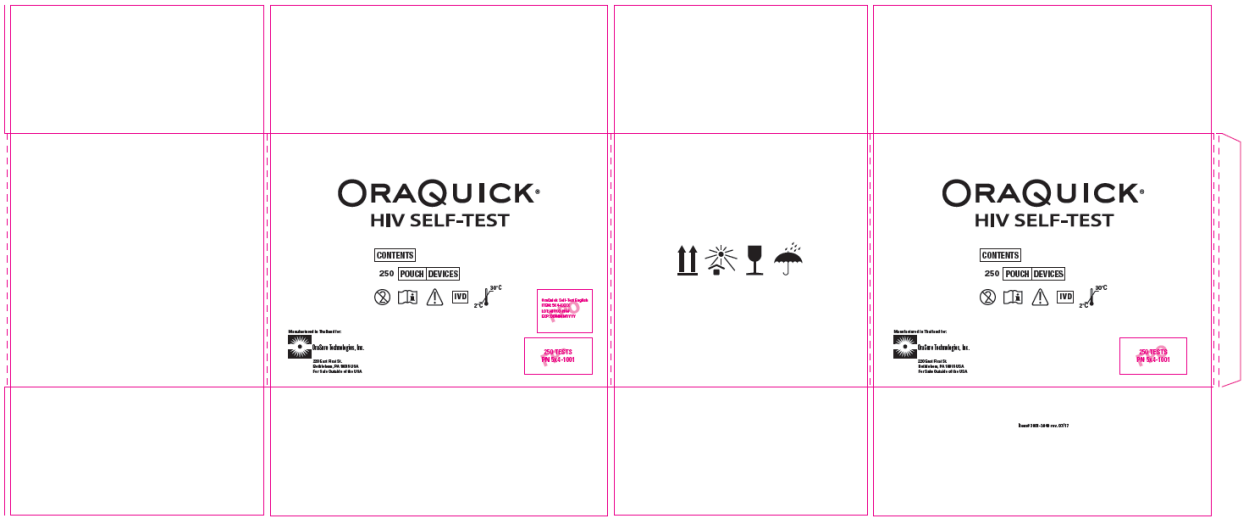
Inner Pouch 3001-3036 rev. 04/17 with JIT



Outer Pouch rev. 07/17

50 Count Shipper Box 3001-3039 rev 07/17





Instructions for use/ Directions for use 3001-3031 rev 07/17

PRODUCT INFORMATION

REF 6X4-1000, 6X4-1001

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

INTENDED 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 from infected individuals.

SUMMARY OF THE TEST

The 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. The 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.
This is called the control line.

TEST PERFORMANCE

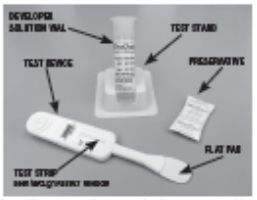
In a clinical study, 400 people who were unaware of their HIV status were given the OraQuick® HIV Self-Test to use. The results were compared to a 4th generation laboratory test. The laboratory results show that a total of 76 people were HIV positive and 324 people were HIV negative. The comparison of results was as follows:

- 100% of people (76 out of 76) correctly reported their result as positive. This means that 76 people infected with HIV correctly interpreted the result as HIV positive.
- 99.1% of people (321 out of 324) correctly reported their result as negative. This means that 3 out of 324 people not infected with HIV reported a positive test result. This is called a false positive.
- In addition, only 0.7% of study subjects (3 out of 410) failed to obtain a test result.

KIT CONTENTS

- One pouched kit containing:
  - Divided Pouch (5X4-0004) with single use Test Device, Preservative and a Developer Solution Vial
  - Test Stand
  - 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. 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.

30 °C 2 °C 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°-30° C (36°-86° F).
- This test should be performed at temperatures in the range of 15°-37° C (59°-99° F).

LIMITATIONS OF THE TEST

- 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 (VII) 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.

QUESTIONS & ANSWERS

1. ***What does the test do?***
   The OraQuick® HIV Self-Test is an in-vitro diagnostic self-test for HIV (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 as true.
2. ***What is a 'risk event' for HIV?***
   A risk event is defined by any of the below activities:
   - 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
3. ***How soon after a risk event can I test myself?***
   You can test any time; if you are using this test earlier than 3 months since a risk event and your test is 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 shouldn't 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 OraQuick® HIV Self-Test to use. The results were compared to a 4th generation laboratory test. The laboratory results show that a total of 76 people were HIV positive and 324 people were HIV negative. The comparison of results was as follows:
- 100% of people (76 out of 76) correctly reported their result as positive. This means that 76 people infected with HIV correctly interpreted the result as HIV positive.
- 99.1% of people (321 out of 324) correctly reported their result as negative. This means that 3 out of 324 people not infected with HIV reported a positive test result. This is called a false positive.
- In addition, only 0.7% of study subjects (3 out of 410) failed to obtain a test result.

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 be tested at least once per year (World Health Organization recommendation). **If you feel you are at increased risk for being infected with HIV, you should test regularly.**

8. ***What does a negative result mean?***
A negative result means that the test has not detected any antibodies; however, it may take up to 3 months from a risk event for the test to detect HIV. If it has been **at least 3 months** since you had a risk event and you followed the Directions for Use carefully, you likely do not have HIV. If it has been less than **3 months** since you had a risk event, **wait the full 3 months** since the risk event to take the test or go to your health facility.

9. ***What should I do if I get a negative result?***
If you have not had any risk events within the past **3 months**, and you followed the Directions for Use carefully, then you are most likely HIV negative. If you did not follow the Directions for Use carefully, you should take the test again to be sure your result is correct. If you had any risk events in the past **3 months**, you could be in the 'window period'. The window period is when a person has been infected with HIV, but their body has not made antibodies yet. **If you think you may have been exposed to HIV within the past 3 months**, you should retest for HIV **3 months** following any risk event. If you continue to engage in risk events that could put you at risk for HIV, you should test on a regular basis.

10. ***What does a positive result mean?***
A positive result means that you may have HIV. **Additional testing must be conducted at a health facility to confirm the result.**

11. ***What should I do if I get a positive result?***
You need to follow up with a health facility to get additional testing to confirm the result. At that time your local clinic, doctor, or healthcare professional will discuss the next steps that need to be taken.

12. ***Can I get an incorrect 'false' negative result with this test?***
An incorrect 'false' negative result can occur for any of the following reasons:
- If you had a risk event less than 3 months prior to taking the test
- Incorrectly reading test result as negative
- Not following the Directions for Use carefully
- If you wore dental products such as dentures or any other products that cover your gums while swabbing your gums
- If you are taking an oral PrEP regimen or if you are on HIV treatment (ARV)

13. ***Can I get an incorrect 'false' positive result with this test?***
An incorrect or 'false' positive result can occur for any of the following reasons:
- Incorrectly reading test result as positive
- Not following the Directions for Use carefully
- Not waiting 15 minutes after eating, drinking, or 30 minutes after using oral care products before taking the test
- Having received an HIV vaccine
- Swiping each gum several times during oral collection

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 if I am taking medicine to prevent HIV (oral PrEP)?***
If you are taking oral PrEP for HIV, you may get false result.

16. ***How can I tell if my test is working correctly?***
If your test is working correctly you will see a line next to the "C" on your test device. If there is no line next to the "C" your test did not work.

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS
As part of the oral fluid clinical studies, information was collected from the participants regarding concurrent diseases or medical conditions, oral pathologies, non-HIV viral infections, and other factors (e.g., use of tobacco products, mouthwash within 24 hours of testing, concomitant medications, dental fixtures, and food or drink immediately prior to testing). In a separate study of 40 individuals, consumption of alcohol, brushing of teeth, use of mouthwash or smoking tobacco 5 minutes prior to testing, were shown to have no effect on test specificity. **If you are HBV, HCV or HTLV (I/II) positive, you may get a false result.** 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.

EXPLANATION OF SYMBOLS

LOT Batch Code	REF Catalog Number	Caution, Consult Accompanying Documents	Consult Instructions for Use
Do Not Reuse	IVD *In Vitro* Diagnostic Medical Device	Manufacturer	EXP Date of Expiration
Temperature Limitation	Use By		DOM Date of Manufacturing

Manufactured in Thailand for

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Item# 3001-3031 rev. 07/17