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

ENGLISH

ORAQUICK® HIV SELF-TEST

INSTRUCTIONS FOR USE

You must follow the test directions carefully to get an accurate result.

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.

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.

VIEW INSTRUCTIONS
oraquick.com

HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT

1

YOU WILL NEED A WAY TO TIME THE TEST

2

Kit contains: **test kit**, **test stand**, **instructions for use** and **disposal bag**. Remove these items to begin testing.

3

Your test kit contains two pouches.

4

Tear open the pouch containing the tube.

5

Remove the cap.

6

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

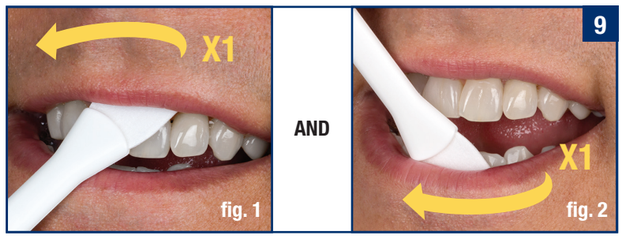
7

Slide the tube into the **stand**.

8

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

9

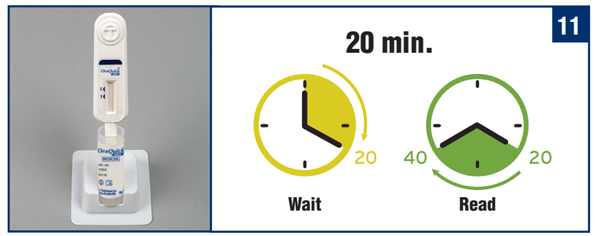


Press the **Flat Pad** firmly against your gum and swab it along your **upper gum once** (fig. 1) and **your lower gum once** (fig. 2).

10

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

11



LEAVE IT THERE for 20 MINUTES before reading the results. DO NOT read the result after 40 minutes.

INTERPRETING RESULTS Read test results in a well-lit area

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.

→ ***As soon as possible . . .***

Visit your nearest HIV Testing Centre or Health Facility

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. → Seek regular testing. If you may have been exposed to HIV, test again in 3 months.

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.**

→ The test did not work properly.

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

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.

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.

Item #3001-3224-70
rev. 04/21B

ORAQUICK® HIV SELF-TEST PRODUCT INFORMATION 1001-0600U 1001-0600

The OraQuick® HIV Self-Test is an *in-vitro* diagnostic home-use test for HIV (HIV-1 and HIV-2) in oral fluid. This test works by looking for your body's response (antibodies) to fighting the HIV virus.

IMPORTANT

- **Please follow the testing directions carefully to be sure the results are correct**
- **A positive result with this test does not mean that you are definitely infected with HIV, but rather that additional testing should be done in a medical setting**
- **A negative result with this test does not mean that you are definitely not infected with HIV, particularly when exposure may have been within the previous 3 months**
- **If your test is negative and you engage in activities that put you at risk for HIV on a regular basis, you should test regularly**
- **This product should not be used to make decisionson behavior that may put you at increased risk for HIV**

Biological principles of the test

The OraQuick® HIV Self-Test is a manually performed, visually read, 20 minute immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2. The assay test strip contains synthetic peptides representing the HIV envelope region and a goat-anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test (T) zone and the Control (C) zone, respectively.

Test performance in untrained users

In a clinical study, **494** people who were unaware of their HIV status were given the OraQuick® HIV Self-Test to use. Six (6) individuals were removed from the accuracy calculation because they did not report a result; however, they were included in the 1.8% of individuals that failed to get a test result.

- 99.2% of people (484 out of 488) correctly reported their test results. The laboratory test (OraQuick *ADVANCE*® HIV-1/2 Antibody Test) and OraQuick® HIV Self-Test found the same result. This means that 4 out of 488 people reported their result incorrectly. Of the 4 people who reported incorrect results, there was 1 person who reported a positive result with the OraQuick® HIV Self-Test instead of a negative result and 3 people who reported that the test did not work with the OraQuick® HIV Self-Test
- In addition only 1.8% of study subjects (9 out of 494) failed to obtain a test result with the OraQuick® HIV Self-Test

Warnings and precautions

- For individuals 18 years of age and older
- Make sure you are taking the test in a place with good lighting
- If you are HIV positive, or are on treatment or preventive treatment for HIV, this test is not meant for you
- 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 the research group
- If the tamper-evident seal has been broken or if any of the package contents are missing, broken, or have been opened, do not use this test
- If today is after the expiration date on the outside of the box, do not use this test
- Do not open any of the packets until you are ready to begin your test
- Do not eat or drink for at least 15 minutes before starting the test or use mouth cleaning products (such as mouthwash, toothpaste or whitening strips) 30 minutes before starting the test
- Remove dental products such as dentures or any other products that cover your gums prior to the oral collection
- Do not use the test if it has been exposed to household cleaning products
- Do not use this test if it has been stored outside the acceptable temperature of 2°-27°C (36°-81° F)

If any components are missing from the kit or if any of the pouches have been opened, do not use the test.

Materials needed but not provided:

- A timer, watch or something that can time 20 to 40 minutes
- Eyeglasses – if you use eyeglasses to read, you should wear them while reading your test results

QUESTIONS & ANSWERS

1. ***What does the test do?***
   The OraQuick® HIV Self-Test is an *in-vitro* diagnostic home-use test for HIV (HIV-1 and HIV-2) in oral fluid. This test works by looking for your body's response (antibodies) to fighting the HIV virus. A positive result is preliminary and follow-up confirmatory testing is needed.
2. ***How soon after a risk event can I test myself?***
   This test detects HIV infection if used **3 months after a risk event**. If you want to be tested before **3 months**, you should go to your local clinic or healthcare professional.
3. ***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 defend against the HIV virus by producing antibodies to it. These antibodies can be found in your blood or oral fluid. It takes your body up to **3 months** to produce these antibodies at levels that can be detected by this test.
4. ***Will the results of this test tell me if it is safe to have unprotected sex?***
   No, you should not use this test to make decisions on behavior that may put you at increased risk for HIV, such as having unprotected sex.
5. ***How can I tell that my test is working correctly?***
   If your test is working correctly you will see a line next to the "C" on your test stick. If there is no line next to the "C" your test did not work.
6. ***Do any drugs or medications affect the test?***
   To date there is no evidence that the use of antibiotics or medications (not HIV related) affect the test results. Individuals on treatment for HIV should not use this test as this will cause a false negative result with this test.
7. ***What can cause a false negative result?***
   A false negative result can occur for the following reasons:
   - If you have had a recent risk event and your body is not producing antibodies yet
   - Incorrectly reading test result as negative
   - Not following the test directions carefully
   - If you wore dental products such as dentures or any other products that cover your gums while swiping your gums
8. ***What can cause a false positive result?***
   A false positive result can occur for any of the following reasons:
   - Incorrectly reading test result as positive
   - Not following the test directions carefully
   - Not waiting 30 minutes after eating, drinking, or using oral care products before taking the test
   - If you have participated in a HIV vaccine clinical trial
   - Swiping gums multiple times during collection

Performance Characteristics in trained users

Performance data was generated with the OraQuick *ADVANCE*® HIV-1/2 Antibody Test.

Sensitivity

Detection of Antibodies to HIV-1 in Specimens From Individuals Infected with HIV-1.

Oral Fluid

A sensitivity study was performed using freshly obtained oral fluid specimens collected from 597 individuals reported to be infected with HIV-1. Of the 597 specimens that were identified as seropositive using licensed confirmatory testing, 597 gave a reactive result on the OraQuick *ADVANCE*® HIV-1/2 Antibody Test. The sensitivity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test in oral fluid specimens was calculated to be 597/597= 100%.

TABLE 1. Summary of Sensitivity Studies

Specimen	Reactive	Total N	Sensitivity
Oral Fluid	597	597	100,0%

Reactivity with HIV-1 Specimens From Various Geographic Regions

To assess the sensitivity of the OraQuick *ADVANCE*® HIV-1/2 Antibody Test for HIV-1 specimens from various geographic regions, 119 specimens representing HIV-1 Subtypes A, B, C, D, E, F, G, H, J and Group O were tested and all were reactive using the OraQuick *ADVANCE*® HIV-1/2 Antibody Test. A commercially available worldwide plasma panel was utilized for this testing.

Reactivity with HIV-1 Seroconversion Panels

Thirty HIV-1 seroconversion panels were tested in comparison with CE marked anti-HIV EIA tests. Each panel consisted of sequential serum/plasma specimens obtained from a single individual during seroconversion. The thirty seroconversion panels consisted of 235 specimens. The results of this study are shown in Table 2. In this study, the OraQuick *ADVANCE*® HIV-1/2 Antibody Test detected seroconversion, on average, at approximately the same time as the CE marked EIA.

TABLE 2. Comparison of OraQuick *ADVANCE*® HIV-1/2 Antibody Test and Licensed Anti-HIV EIA Tests Using Seroconversion Panels

Number of Panels	Reactive
17	**OraQuick® = Reference EIA**
13	**OraQuick® < Reference EIA**

The average differential was 2.5 days later (95% CIs: 1.2 to 3.8 days) for the OraQuick *ADVANCE*® HIV-1/2 Antibody Test.

Detection of Antibodies to HIV-2 in Specimens From Individuals Infected with HIV-2

A total of 104 repository specimens confirmed to be HIV-2 antibody positive by licensed HIV-2 EIA and supplemental test methods including Western blot and RIPA were obtained from various sources. OraQuick *ADVANCE*® detected 104/104 (100%) of the specimens from individuals confirmed as positive for HIV-2 antibodies. Two additional studies were performed to assess the sensitivity of OraQuick *ADVANCE*® in a known HIV-2 population. Three HIV-2 infected individuals located in the USA and 13 HIV-2 infected individuals located in Guinea-Bissau, Africa were tested using fingerstick whole blood and oral fluid with OraQuick *ADVANCE*® tests. Fingerstick whole blood and oral fluid samples from all subjects were reactive on the OraQuick *ADVANCE*® test. Combining the number of OraQuick *ADVANCE*® reactive results obtained from all studies, the sensitivity of the OraQuick *ADVANCE*® HIV-1/2 Antibody Test for the detection of antibodies to HIV-2 was calculated to be 120/120= 100%.

SPECIFICITY

Oral Fluid

A specificity study was performed at four clinical trial sites using freshly obtained oral fluid specimens collected from 606 previously unscreened individuals at low risk for HIV-1 infection. All of the 606 specimens were correctly non-reactive using the OraQuick *ADVANCE*® HIV-1/2 Antibody Test. Of the 106 HIV antibody-negative specimens from the four study sites that examined populations at high risk for HIV-1 infection, the OraQuick *ADVANCE*® test was non-reactive for 105.

A separate study conducted by the Centers for Disease Control and Prevention (CDC) evaluated oral fluid samples collected from 1679 individuals of unknown HIV status. The OraQuick*ADVANCE*® HIV-1/2 Antibody Test gave non-reactive results for 1662 of the 1666 specimens identified as true negative samples.

Combining the number non-reactive results obtained from both studies, the specificity of the OraQuick *ADVANCE*® HIV-1/2 Antibody Test in these studies was calculated to be 2373/2378= 99,8%.

TABLE 3. Summary of Specificity Studies

Specimen	Total N	OraQuick® Non-Reactive	True Negative	Specificity
Oral Fluid	2378	2373	2378	99,8%

Performance Characteristics in untrained users

Performance data was generated with the OraQuick® HIV Self-Test, which is the same test as the OraQuick *ADVANCE*® HIV-1/2 Antibody Test, labeled for use.

Sensitivity

In a clinical study, **494** people who were unaware of their HIV status were given the OraQuick® HIV Self-Test to test themselves. 9 of the 494 study subjects were removed from the calculation because they failed to obtain a test result with the OraQuick® HIV Self-Test. The reseachers compared the OraQuick® HIV Self-Test results with laboratory results performed by a trained professional.

TABLE 4. Summary of Sensitivity Results

Specimen	Reactive	Total N	Sensitivity
Oral Fluid	12	12	100,0%

TABLE 5. Summary of Specificity Results

Specimen	OraQuick® Non-Reactive	True Negative	Total N	Specificity
Oral Fluid	472	473	473	99,8%

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS

To assess the impact of unrelated medical conditions or interfering substances on the sensitivity of the OraQuick *ADVANCE*® HIV-1/2 Antibody Test, 200 serum/plasma specimens from a variety of medical conditions unrelated to HIV-1 infection and 100 specimens with interfering substances were spiked with an HIV-1 positive specimen to give a level of reactivity in the low positive range. All spiked specimens gave reactive results.

To assess the impact of unrelated medical conditions or interfering substances on the specificity of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 321 serum/plasma specimens from a variety of medical conditions unrelated to HIV infection and 119 specimens with interfering substances were analyzed. One specimen from subjects known to be positive for EBV, for HBV, or for rheumatoid factor, one from a multiparous woman, and three specimens from known HAV infected subjects gave false positive results.

TABLE 6. Medical Conditions Unrelated to Hiv Infection

Interfering Substances (n=119)	OraQuick® Reactive	OraQuick® Non-Reactive
Elevated Bilirubin	0	20
Elevated Hemoglobin	0	20
Elevated Triglycerides	0	20
Elevated Protein	0	20
Bacterially Contaminated	0	25
Visual Hemolysis (hemolytic)	0	5
Icteric	0	5
Lipemic	0	4
Medical Condition (n=321)	**OraQuick® Reactive**	**OraQuick® Non-Reactive**
Multiparous women	1	14
Anti-nuclear antibody (ANA)	0	17
Lupus	0	15
Rheumatoid Factor	1	17
Cytomegalovirus (CMV)	0	15
Epstein Barr Varius (EBV)	1	14
Hepatitis A Virus (HAV)	3	27
Hepatitis B Virus (HBV)	1	16
Hepatitis C (HCV)	0	15
Human T-cell Lymphotropic Virus Type I (HTLV-I)	0	15
Human T-cell Lymphotropic Virus Type II (HTLV-II)	0	15
Rubella	0	15
IgG Gammopathies	0	13
IgM Gammopathies	0	12
Syphilis	0	15
Toxoplasmosis	0	15
Tuberculosis	0	15
Influenza	0	10
Multiple Transfusions	0	10
Hemophiliacs	0	10

TABLE 6. Medical Conditions Unrelated to Hiv Infection (continued)

Herpes Simplex Virus	0	5
Cirrhosis	0	5
Dialysis Patient	0	4
Colon Cancer	0	4
HTLV I/II	0	2
Chlamydia	0	3
Anti-sci or anti-mp Antibody	0	3
Breast Cancer	0	1
Anti-DNA Antibody	0	1
Gonorrhea	0	1

EXPLANATION OF SYMBOLS

LOT Batch Code	IVD *In Vitro* Diagnostic Medical Device	Consult Instructions for Use
Do Not Reuse	Use By	EXP Date of Expiration
Temperature Limitation	Caution, Consult Accompanying Documents	Date of Manufacturing
REF Catalog Number	Manufacturer	EC REP Authorized Representative in the European Country
DEV SOL VIAL Developer Solution Vial	DEVICES Devices	

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