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**PACKAGE INSERT****For *in-vitro* diagnostic use**

The OraQuick® In-Home HIV 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.**
- **You must be 17 or older to use this test.**
- **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 decisions on behavior that may put you at increased risk for HIV.**

**Test Performance**

In a clinical study, 4,999 people who were unaware of their HIV status were given the OraQuick® In-Home HIV Test to take home and use. The researchers compared the OraQuick® In-Home HIV Test results with laboratory test results performed by a trained professional. The laboratory based results show that a total of 96 people were HIV positive and 4,903 people were HIV negative. The comparison of results was as follows.

- 99.9% of people (4,902 out of 4,903) correctly reported a negative test result. The lab and OraQuick® In-Home HIV Test found the same result. This means that 1 out of 4,903 people not infected with HIV reported a positive test result even though that person was really not infected with HIV. This is called a "false positive."
- 91.7% of HIV positive people (88 out of 96) tested reported a correct test result. This means that 8 out of 96 people who actually were infected with HIV reported a negative test result even though they had HIV. This is called a "false negative."
- In addition only 1.1% of study subjects (56 out of 5,055) failed to obtain a test result.

**Warnings and Precautions**

- Most people feel a little bit anxious when taking an HIV test. But, if you feel very anxious 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.
- 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 the expiration date of the test is past the date printed 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, drink or use oral care 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 36°-80° F (2°-27°C).

**Kit contents (one of each)**

- Pouch containing a Single Use Test Device
- Pouch containing a Test Tube filled -1 mL of liquid
- Disposal Bag
- Pencil
- Testing Directions attached to plastic box
- Pre-Test Booklet – HIV, Testing & Me
- Post-Test Booklet – What your results mean to **You!**
- Package Insert

If any components are missing from the kit or if any of the pouches have been opened, do not use the test. Please contact the OraQuick® Support Center toll free at 1-866-436-6527.

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® In-Home HIV 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. What kinds of events put me at risk for HIV?**

- 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?**

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 doctor or local healthcare provider. If you do not know where to get tested, you can call the OraQuick® Support Center toll free at 1-866-436-6527 and a Support Center representative can provide you with the name of a healthcare provider or a clinic in your area.

**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 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.

**5. Can someone help me with directions on how to take the test correctly?**

Yes, the OraQuick® Support Center is available 24 hours a day, 7 days a week, toll free at 1-866-436-6527. A Support Center representative will assist you with any questions you may have on performing the test or connecting you with a healthcare provider in your area. Additionally you can go to [www.oraquick.com](http://www.oraquick.com) to view a video on how to take the test. All calls are completely confidential.

**6. Can someone help me read my results?**

The OraQuick® Support Center is available 24 hours a day, 7 days a week, toll free at 1-866-436-6527. A Support Center representative will assist you with any questions. Since this is a visually read test, they cannot actually read your results; however, they can help you to understand your test result.

**7. How often should someone test for HIV?**

How often you should get tested for HIV depends on your circumstances. If you have never been tested for HIV, you should be tested at least once.

The Centers for Disease Control and Prevention (CDC) recommends being tested at least once a year if you do things that can result in HIV infection. These include:

- 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

If you have been exposed to events that could result in HIV infection, you should test **3 months** after the event. **If you feel you are at risk of being infected with HIV, it is a good idea to test regularly.**

**8. What does a negative result mean?**

A negative result means that the test has not detected HIV antibodies (your body's way of fighting the virus). If it has been **at least 3 months** since you have had a risk event and you followed the directions carefully, you likely do not have HIV. However, as with any test, there is a chance for false results. For this test 8 out of 96 people who actually were infected with HIV reported a negative test result even though they had HIV. This is called a "false negative." To reduce the chance of false results, be sure to use the test correctly. If it has been less than **3 months** since you have had a risk event, **wait until the full 3 months** have passed to take the test. If you did not follow the directions carefully, you should take the test again to be sure your result is accurate.

**9. What should I do if I get a negative result?**

Please refer to the booklet "**What your results mean to You**" to learn ways that you can reduce your risks. **If you feel you are at risk of being infected with HIV, it is a good idea to test regularly.**

**10. 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.

**11. What is a false negative?**

When a person reads his/her test result as negative, but the true HIV status of the person is positive (infected with HIV).

**12. What can cause a false negative result?**

A false negative result can occur for the following reasons:

- If you have had a risk event less than **3 months** prior to taking the test
- 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

**13. What does a positive result mean?**

A positive result means that you may have HIV. **A doctor, clinic or healthcare professional must confirm your OraQuick® In-Home HIV Test result.**

**14. What should I do if I get a positive result?**

You need to follow up with a doctor or healthcare provider to get a confirmatory test. At that time your doctor or healthcare provider will discuss the next steps that need to be taken. You should read the booklet "**What your results mean to You!**"

If you need help locating a healthcare provider in your area, please call the OraQuick® Support Center toll free at 1-866-436-6527.

**15. What is a false positive result?**

When a person reads his/her test result as positive and the true HIV status of the person is negative (not infected with HIV).

**16. 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 each gum more than once during oral collection

**17. Is there a way to find out where I can get additional help or care?**

You can call the OraQuick® Support Center toll free at 1-866-436-6527 and a Support Center representative will be able to provide you with a list of healthcare providers in your area. You may also go to [www.oraquick.com](http://www.oraquick.com).

**18. 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.

**19. What should I do if my test is not working?**

If you believe your test may not be working correctly, please call the OraQuick® Support Center toll free at 1-866-436-6527 and a Support Center representative will assist you.

**20. How can I get additional information about HIV/AIDS?**

The OraQuick® Support Center can provide you with information about HIV/AIDS. The call center is available 24 hours a day, 7 days a week, and 365 days a year. The toll free number for the OraQuick® Support Center is 1-866-436-6527 or you can go to [www.oraquick.com](http://www.oraquick.com).

**21. 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; however, individuals on treatment for HIV should not use this test.

**OraSure Technologies, Inc.**220 East First Street • Bethlehem, PA 18015 USA  
[www.oraquick.com](http://www.oraquick.com)

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