91.7% of HIV positive people (88 out of 96) tested reported a correct test result. This means that

- Pouch containing a Test Tube filled -1mL of liquid
- Pre-Test Booklet – HIV, Testing &
- Pouch containing a Single Use Test Device
- Testing Directions attached to plastic box

Kit contents
• Do not use the test if it has been stored outside the acceptable temperature of 36°-80°F (2°C-27°C).

- Item # 3001-2597 rev. 06/12
- OraSure Technologies, Inc.
- 220 East First Street • Bethlehem, PA 18015 USA
- www.oraquick.com

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

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

- 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 result?

- When a person tests 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 were infected by contaminated items 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 talk 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!”

15. What is a false positive result?

- When a person tests 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
  - If you have another medical condition

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.

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” you should not use the test.

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

- If your test result is not clear or you need help interpreting your results, please call the OraQuick® Support Center toll free at 1-866-436-6527 and a Support Center representative will assist you.

Risks
- You should not use the test if you have been exposed to events that could result in HIV infection. These include:
  - Having been diagnosed or treated for hepatitis, tuberculosis or a sexually transmitted disease
  - Engaged in oral sex

Materials needed but not provided:
• A timer, watch or something that can time 20 to 40 minutes
• Eyeglasses – if you use eyeglasses, 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.

2. What kinds of people use the test 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 3 days after a risk event. If you want to be tested before 3 days, you should go to your local healthcare provider or call the OraQuick Support Center 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.

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.

6. 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.

7. How do I use the test?

- 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, 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.

8. 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.

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 risk of being infected with HIV.

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 result?

- When a person tests 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 other products that cover your gums while swiping your gums

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  - 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
  - If you have another medical condition

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.

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” you should not use the test.

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 Information be used for purposes of research?

- 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, 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.

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.
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.

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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.

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• 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 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 right away. If you are unsure whether you were tested, you can call the OraQuick® Support Center toll free at 1-866-436-6527 and a Support Center representative will assist you with any questions. Since this is a visual read test, they cannot actually read your results; however, they can help you to understand your test result.

4. 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. Since this is a visually read test, they cannot actually read your results, however, they can help you to understand your test result.

5. 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.

6. What does a positive result mean?
A positive result means that you may have HIV. If you feel you are at risk of being infected with HIV, it is a good idea to test regularly.

7. 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) in your oral fluid. It has been at least 3 months since you 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 reason, 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.”

8. What should I do if I get a negative result?
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 is not working. If your test is not working, please call the OraQuick® Support Center toll free at 1-866-436-6527 and a Support Center representative will assist you with any questions. Since this is a visual read test, they cannot actually read your results; however, they can help you to understand your test result.

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 risk of HIV. 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
• Incorrectly reading test directions carefully
• If you were 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 talk 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!”

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 it may not mean that you are infected with HIV, but rather that additional testing should be done.

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
• If you have taken a medication on your own

17. Is there a way to find out where I can get additional help or care?
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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.
The OraQuick® In-Home HIV Test is an in-vitro diagnostic 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.

**Test Performance**

In a clinical study, 4,999 people 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 researchers found 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 did not have HIV detected with the lab test even though the person was really not infected with HIV. This is called a "false negative." *(96/4,903)*
- 3.1% of HIV positive people (30 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 positive." *(30/96)*
- In addition only 1.1% of study subjects (56 out of 5,055) failed to obtain a test result.