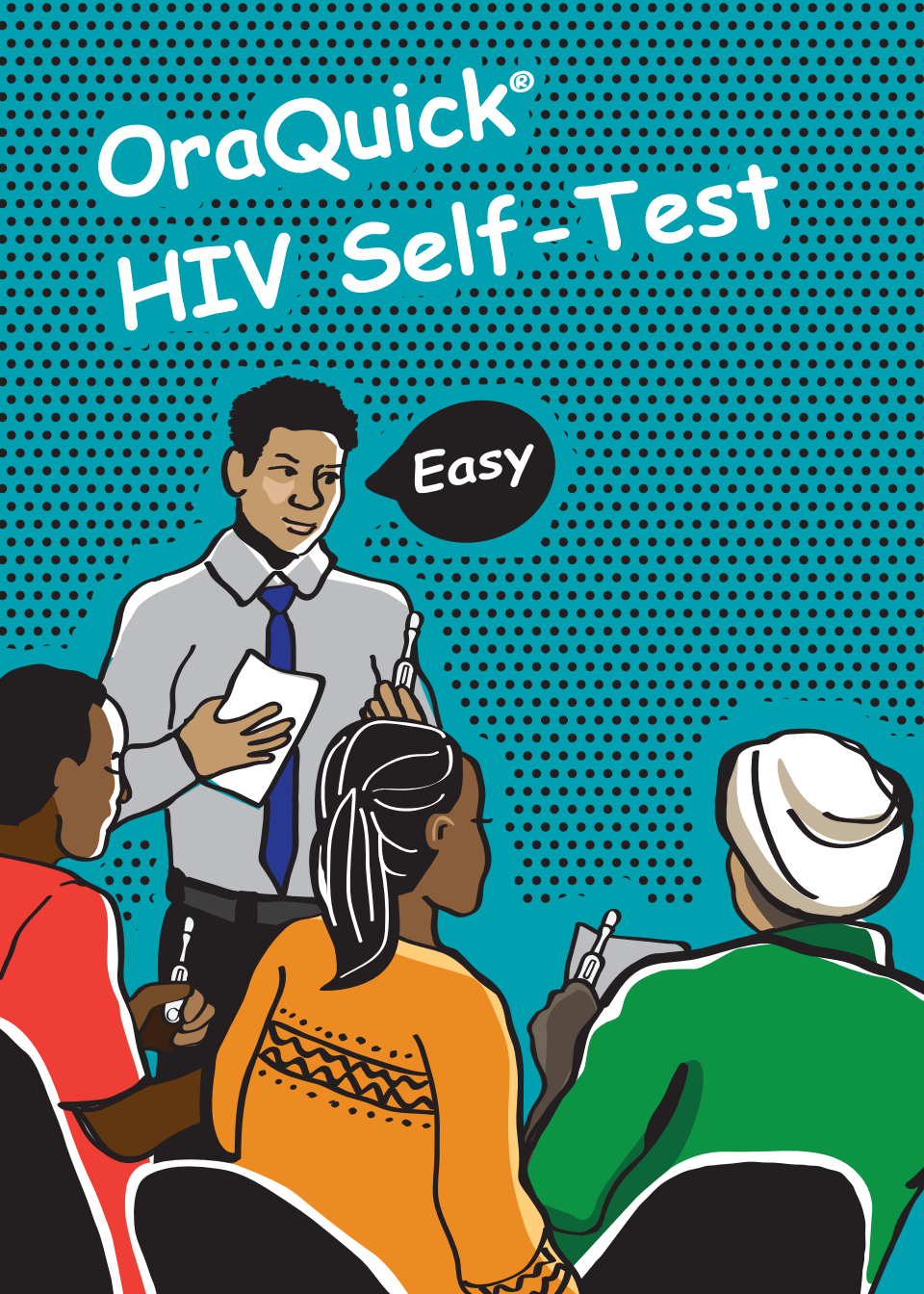
ORAQUICK®
HIV SELF-TEST

Information Manual

Do the test.
Know your status.
Own your health.

OraQuick® HIV Self-Test



OraQuick® Information Manual

This booklet is a guide to understanding who should be tested for HIV and how to test for HIV using the OraQuick HIV Self-Test.

The OraQuick HIV Self-Test

The OraQuick HIV Self-Test is a private and accurate way to test for HIV in your own home. It is the same test used by healthcare professionals and approved by the World Health Organization (WHO).

The test allows you to test for HIV by using oral fluid instead of needles or fingerstick blood.

The OraQuick HIV Self-Test is a single-use test that should only be used to test for HIV and should not be used for other purposes.

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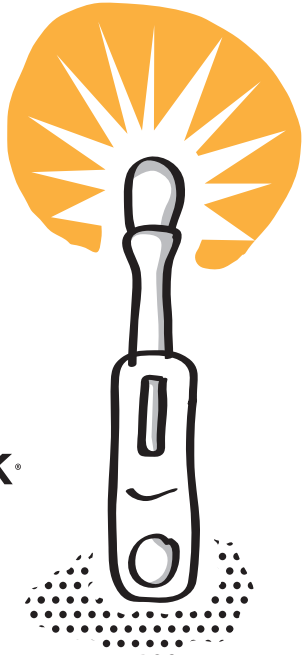
HIV SELF-TEST



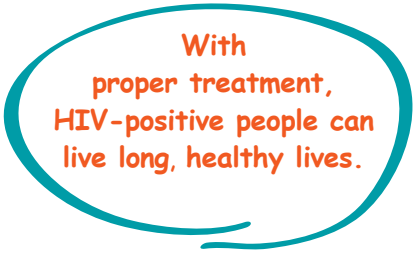
What is HIV?

HIV is a virus. Some viruses, like the ones that cause colds or the flu stay in the body for a few days. HIV never goes away.

A person who is living with HIV is considered 'HIV-positive'. Once a person is HIV-positive, they will always be HIV-positive.[1] With new treatments, many HIV-positive people live long, active lives. People with HIV who take their medicine as prescribed daily can successfully control the virus. When the virus is fully controlled by treatment, it is unlikely that HIV will be transmitted to a sexual partner, drug injection partner or child during pregnancy or breastfeeding.[2]

How HIV is transmitted?

HIV is spread from a person who is HIV-positive to another person by contact with bodily fluids such as blood, semen, vaginal secretion and breast milk.[2]

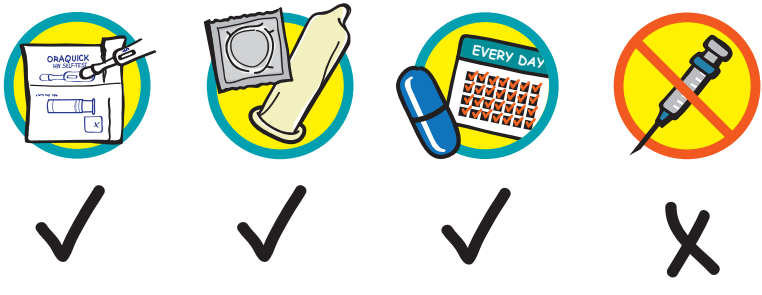


1 *https://www.cdc.gov/hiv/statistics/overview/ataglance.html*
2 *https://www.who.int/news-room/fact-sheets/detail/hiv-aids*

HIV is preventable.

You can reduce your risk by:

- Getting tested and knowing your partner(s) HIV status
- Practicing safe sex:
  - Use condoms
  - Talk to you healthcare professional about PrEP and PEP
- Using clean needles and syringes
- Supporting a partner with HIV to stay adherent to treatment



Early detection can lead to early treatment and better health outcomes. Many people with HIV on treatment live long, normal and healthy lives.

Take the test and help prevent the spread of the HIV virus.

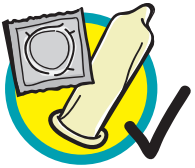
Who can get HIV?

Anyone can get HIV; your race, gender, religion, and sexual orientation does not matter.

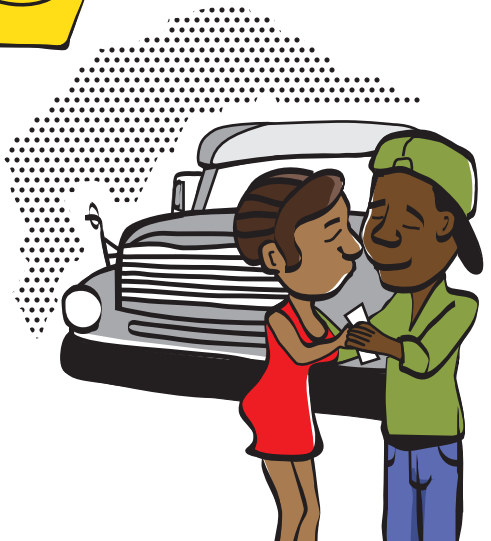
Everyone should test at least once in their lifetime. In high burden settings, retesting every year is recommended. If you are at a high, ongoing risk, you should test more regularly.

The following are examples of activities that increase the chances of getting HIV.

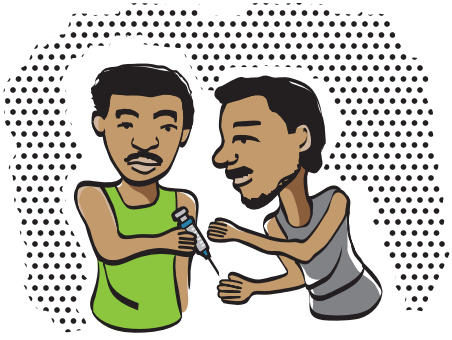
Multiple sex partners or sex without a condom



Use a condom



Exchanging sex for money



Sharing dirty needles during drug use

Use clean needles and syringes

Why test for HIV?

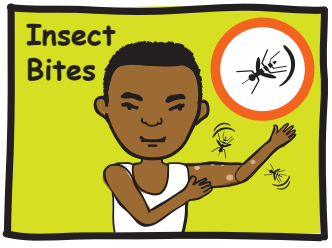
Testing is the first step to preventing the spread of the HIV virus and is important to protect your health, family and future. No matter the result, knowing your status is important.

HIV is no longer a death sentence if you know your status and follow treatment. Regular testing means you can be diagnosed and linked to care more quickly.

Early and consistent access to HIV treatment can reduce the likelihood of you transmitting the disease by 96%.[3]

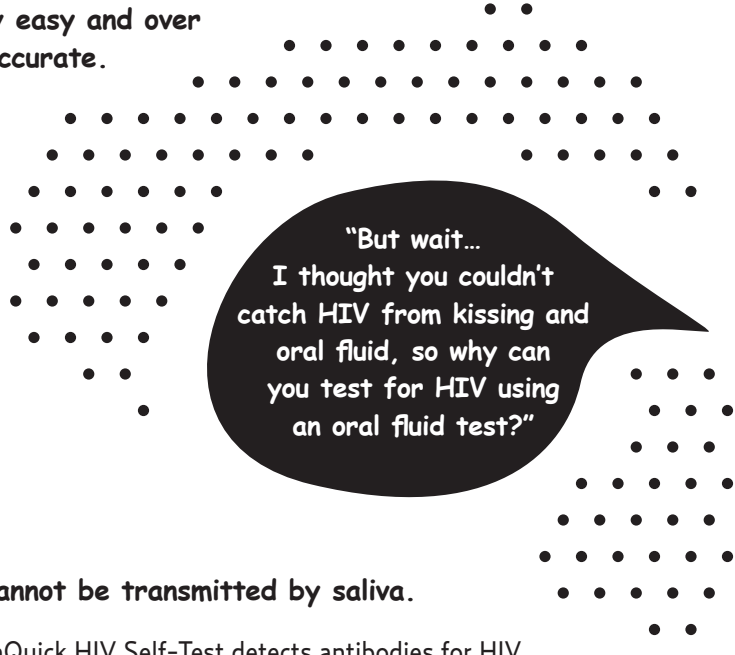
[3] *Cohen MS, et al. HIV treatment as prevention and HPTN 052. Curr Opin HIV AIDS 2012, 7:99-105.*

You CAN'T get HIV from ...



Oral HIV testing and kissing

Testing for HIV using oral fluid is very easy and over 99% accurate.



HIV cannot be transmitted by saliva.

The OraQuick HIV Self-Test detects antibodies for HIV, not the virus itself. These are your body's natural defenders. Antibodies are produced by the body as a response to an infection. There is no risk of getting HIV by taking the OraQuick test.

Testing Together

Test for HIV together

Testing for HIV is an important step in having a long and happy relationship. Knowledge is power. Encourage your partner(s) to test with you. This will allow you to know your status and have the power to plan for a better future.

If you are HIV-negative and your partner is HIV-positive, you can still have a healthy happy relationship!

If both partners are HIV-positive, it is still important to use protection. Contact your local testing centre to find out more.

Find out your status by testing together!

What you need to know about the OraQuick HIV Self-Test

Firstly, HIV cannot be transmitted by saliva.

This test works by detecting antibodies, the body's natural defenders against infection. If you are **infected** by HIV, these antibodies will be present in your blood (this is what blood tests detect) and also in your saliva.

The OraQuick HIV Self-Test will detect these antibodies in your mouth and the test will be **positive**.

If you are **not infected** with HIV, the antibodies will not be present and the test will be **negative**.

However, if you have recently been exposed to HIV (in less than 3 months), your body may not be making antibodies yet.

If the test is taken **less than 3 months since a risk event and the test result is negative**, you should test again 3 months after most recent risk event.

If the test result is positive, you must seek further testing by a trained tester in a facility. If confirmed HIV-positive, treatment should be offered and initiated as soon as possible.

In the result window you will see a line marked "C" and one marked "T".

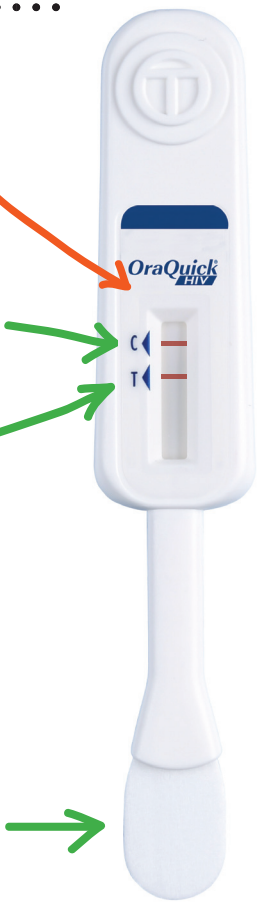
"C" is the control line – a red line will appear here to show the test **worked correctly**. If there is no line at "C" or the background makes it impossible to read the test, it is not working and should be repeated using a new device.

"T" is the test line – a red line will appear here if the test result is **HIV-positive**.

If there is a complete line at "C" AND a complete line at "T", the test is **positive** and you must go to the nearest HIV testing centre or health facility for additional testing and treatment, if needed.

If there is a complete line at "C" and no line at "T", the test is **negative**.

Flat pad – to be inserted in your mouth against gums.



The device

SEE INSTRUCTIONS FOR USE FOR FULL STEP-BY-STEP INSTRUCTIONS ON HOW TO USE THE TEST.

Testing

Testing for HIV is the only way for you to be certain of your HIV status to enable you to make the right decisions about your health.

A negative test result will enable you to take steps to reduce the risk of infection, while a positive test result will empower you to seek treatment and live a normal, healthy life.

Who is at risk for HIV?

If you have been exposed to risk events that could result in HIV infection, you should take an HIV test. People who are at increased risk of being infected with HIV should test regularly.

When to get tested for HIV?

The frequency of testing depends on circumstances and what potential risk activities you engage in. The WHO advises people who are exposed to risk events/activities to get tested at least once a year.

Warning: You may get a false negative result if you are:

- Taking antiretroviral treatment such as pre-exposure prophylaxis (PrEP)
- HIV-positive and on treatment

You should get advice from a medical professional.

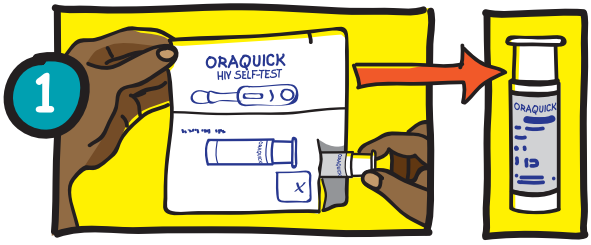
Preparing to take the test

Be sure to follow these directions to get an accurate result:

- Do not eat or drink within 15 minutes before starting the test.
- Do not use oral care products (such as mouthwash, toothpaste or whitening strip) within 30 minutes before starting the test.
- Remove dental products such as dentures or any other products that cover your gums.
- Find a quiet place with good lighting. The test will take 20 minutes.
- Use the directions in the test kit to administer and read the test results correctly.
- Read the instructions carefully.
- Make sure you have a timer or watch that can time 20 to 40 minutes in order to read the results on time.

How to take the test

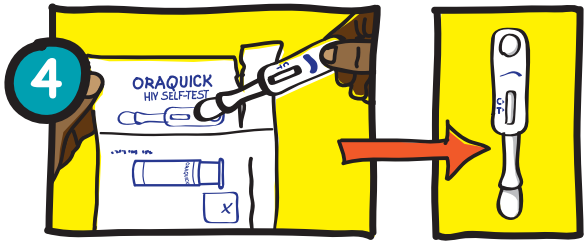
This booklet should not be used in place of the Instructions for Use.



Tear open the pouch containing the tube and remove.

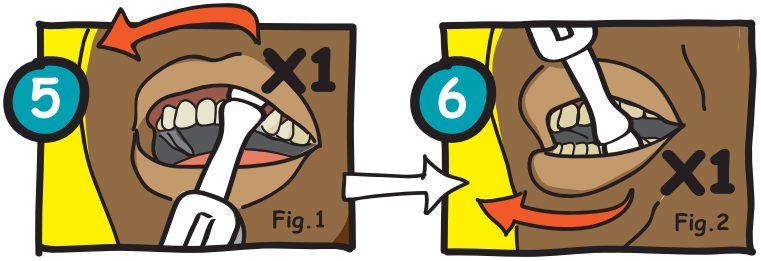
Remove the cap.

Slide the tube into the stand.



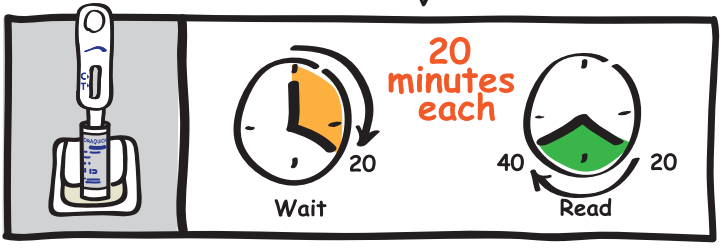
Tear open pouch containing the test device and remove.
DO NOT touch the flat pad with your fingers.

To obtain an accurate result, use the Instructions for Use included with the device when conducting the test.



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).

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



LEAVE IT THERE FOR 20 MINUTES BEFORE READING THE RESULT. DO NOT READ THE RESULT AFTER 40 MINUTES.

Interpreting the results

Interpreting the test results is very simple. To understand the results, compare the test stick to the pictures below and reference the description in the Instructions for Use.

Negative

If there is one line next to the "C" (control) and no line next to the "T" (test), the result is negative.

If the result is negative and it has been at least 3 months since you had a risk event and the directions were carefully followed, **then you do not have HIV.**

If you engage in activities that put you at risk for HIV, you should test regularly.

The most important thing to remember is that HIV is preventable. Understanding how to prevent contracting HIV is important for everyone to understand.

If no lines appear or are faint, reference page 24.

Positive

If there are two lines one next to the "C" and one next to the "T" – the result is positive.

If you are not testing at a clinic or health centre, go to the closest location for confirmatory testing.

A positive result can cause stress, confusion and anxiety. To avoid these feelings, remember:

- You are not alone.
- Easy and effective medical treatments are available to help you live a long and healthy life.
- Having HIV does not mean you have or will get AIDS.
- With effective treatment, you are able to have normal relationships with people who are HIV-negative without the risk of infecting them when taking necessary precautions.
- The key is to identify HIV infection as early as possible to get treatment and remain healthy.

If no lines appear or are faint, reference page 24.

Frequently Asked Questions

FAQs

BEFORE TAKING THE TEST

How does an HIV antibody test work?

An HIV antibody test detects the substance that the body's immune system creates in response to HIV infection. When HIV enters the body, the body starts to produce antibodies as a defense against the virus. However, in the case of HIV, the antibodies can't fight off the infection. But, the presence of antibodies can be used to tell whether you have HIV in your body. Most HIV tests detect the presence of HIV antibodies, not the virus itself.

How can the OraQuick HIV Self-Test use oral fluid for HIV testing, when HIV can't be transmitted by kissing?

HIV transmission does not occur through saliva. The OraQuick test detects antibodies produced in response to HIV infection, not the virus itself. These antibodies can be found in saliva.

How accurate is HIV testing using oral fluid?

Oral fluid HIV tests are very accurate. In studies, the OraQuick HIV Self-Test **detected over 99% of people who were infected with HIV** and people who were not infected with HIV.

What are the advantages of rapid tests for HIV using oral fluids?

Rapid HIV tests that use oral fluid are safe, accurate and provide quick results. They are a good option if you don't like to have blood drawn or your finger pricked.

The risk of exposure to infectious diseases is much lower from oral fluid than from blood. Contact with saliva has never been proven to result in the transmission of HIV.

What could cause a false positive result?

A false positive is when an HIV test shows that you have HIV when you don't actually have it.

Conditions that can lead to a false positive HIV test are:

- Misinterpreting the test as positive.
- Not following the Instructions for Use carefully.
- Not waiting 15 minutes after eating/drinking or not waiting 30 minutes after using oral care/mouth cleaning products before taking the test.
- Having received an HIV vaccine.
- Swiping each gum more than once during oral collection.

A single HIV-positive test result is never enough to provide a definitive diagnosis. All positive self-tests must be followed by further testing from a trained tester in a health facility.

How old do I have to be to use the OraQuick HIV Self-Test?

The OraQuick HIV Self-Test is intended for use by individuals over the age 12 years. If a child is younger than 12 years of age and there is concern that they might have HIV, direct them to a healthcare professional. They will help determine if the child is infected.

Is the test safe for pregnant and/or breastfeeding women?

It is safe to use the OraQuick HIV Self-Test if you are pregnant and/or breastfeeding.

If I wear dentures to cover my gums, can I still take the test?

If you wear dentures, you should follow these steps prior to testing:

1. Remove the dentures.
2. Wash any remaining paste off of the gums.
3. Wait 30 minutes.
4. Perform the test according to the instructions.

Will antibiotics (or other non-HIV related medications) influence the test result?

To date, there is no evidence that the use of antibiotics or medication (other than antiretrovirals) may affect the test results. Please proceed with performing the test as instructed.

TAKING THE TEST

I opened the test and there is no fluid in the tube. What should I do?

If there was no fluid in the test tube when you opened the kit, the kit is defective. We apologize for this inconvenience. Please discard the test kit and contact **customercare@orasure.com**

You can dispose of the test with your regular garbage; no extra precautions are necessary.

There is a small pouch of absorbent material inside the package that contains the test stick. Should I do anything with it?

The small pouch inside the test stick package is designed to prevent moisture from affecting the test stick during storage. It is not to be used when performing the OraQuick test, you can discard it in the regular trash.

I mistakenly/accidentally removed the test stick (or it fell out) from the tube early (before 20 minutes). Will the results be valid?

If you removed the test stick or it fell out, at any point after you placed it in the test tube, the result of the test is not valid even if you immediately replaced the test stick. **The test stick must remain in the test tube for at least 20 minutes as shown in the instructions.** Therefore, do not consider the result accurate.

You can dispose of the test with your regular garbage; no extra precautions are necessary.

Please repeat the OraQuick testing procedure with a new test kit. Carefully follow all the handling and testing instructions.

I left the test stick in the tube longer than 40 minutes. Will the results be accurate?

If you read the test more than 40 minutes after the test stick was placed in the tube, the result of the test is not valid. Do not consider the result accurate.

You can dispose of the test with your regular garbage; no extra precautions are necessary.

Please repeat the OraQuick testing procedure with a new test kit. Carefully follow all the handling and testing instructions.

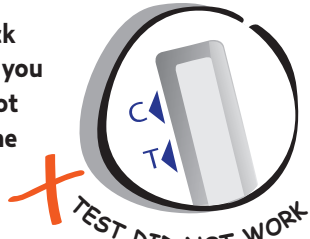
What should I do with the materials after taking the test?

You can dispose of the test and all supporting materials with your regular garbage; no extra precautions are necessary.

UNDERSTANDING THE RESULTS

When I read the test result, there were no markings or colourings on the test stick. What does this mean?

If, in the rare instance, the test stick does not have any lines on it when you read the result, then the test did not work. Therefore, do not consider the result accurate.



You can dispose of the test with your regular garbage; no extra precautions are necessary.

Please repeat the OraQuick testing procedure with a new test kit. Carefully follow all the handling and testing instructions.

My test has a line at the "C" and a very faint line at the "T". What does this mean?

A complete line next to the letter "T" on the test stick, regardless of colour or shade, means a positive test result. You will need a second test to confirm the test result.

Please see your physician or a healthcare provider to obtain a follow up test in a medical setting.

The test result was positive. Can I get HIV by touching, licking or other contact with the saliva on the test stick or the test tube/liquid?

Contact with saliva has never been shown to result in transmission of HIV. Because the test result is positive the individual testing will need a second test to confirm their HIV status. Anyone testing positive should see their physician or a healthcare provider to obtain a follow up test in a medical setting.

Illustration and design: Lorrie Maruscak

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www.self-test.com

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ITEM OQST0501 rev. 02/19