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 (ARVs) you may get a false result.

HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT

YOU WILL NEED A WAY TO TIME THE TEST

Pouch contains: test kit, test stand and instructions for use.

Your test kit contains two pouches.

Tear open the pouch containing the tube.

Remove the cap.

DO NOT pour out the liquid.

DO NOT drink.

Slide the tube into the stand.

HOW TO USE

1. 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.

2. 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).

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

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.

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.

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.

INVALID RESULT

No line next to the “C” (even when there is a line next to the “T”), 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.

DISPOSE

Remove the test stick, put the cap on the test tube and throw away all contents in the normal trash.
The OraQuick® HIV Self-Test is an in-viro 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 in HIV-1 and HIV-2 from infected individuals.

SUMMARY OF THE TEST
The OraQuick® HIV Self-Test is a single-use, qualitative inmuneassay 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 preservative and 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, colored lines form in the "T" (test) area of the device if HIV antibodies are detected. If no HIV antibodies are detected, no lines form. In both cases the test is performed correctly, in a form in the "C" area of the result window. This is called the control line.

TEST PERFORMANCE
In a clinical study, 153 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 153 people were HIV positive and 724 people were HIV negative. Seven (7) people were excluded from the study. The comparison of results was as follows:

- 99.4% of people (152 out of 153) correctly reported their result as positive. This means that 1 out of 153 people infected with HIV were missed by the test. This is called a false negative.
- 96.6% of people (717/734) correctly reported their result as negative. This means that 7 out of 724 people not infected with HIV were missed by the positive test result. This is called a false positive.

Limitations of the 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.

Materials required but not provided: Clock, watch, or timing device

- DO NOT use this test if you are age 11 or younger.
- DO NOT eat or drink for at least 15 minutes before starting the test.
- DO NOT use the test if you are HIV positive.

INTERPRETING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS
As part of the clinical trials, the OraQuick® HIV Self-Test was used on individuals who were taking medication to prevent HIV (oral PrEP), on individuals who had received a blood transfusion or organ transplant, on individuals who were pregnant, on individuals with bleeding disorders, on individuals who were immunocompromised, on individuals with diabetes, and on individuals who were on oral contraceptive pills.

DEFINITION OF SYMPTOMS
- Anticipated symptoms may vary from individual to individual.

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
- Sharing intravenous drug use or needles
- Shared needles or syringes
- Exchanging for money
- Having been diagnosed or tested for hepatitis, tuberculosis or a sexually transmitted disease like syphilis

Additional testing must be conducted at a health facility to confirm the result.

More information can be found on the OraQuick® HIV Self-Test website: www.OraSure.com Item# 3001-3031 rev. 01/18© 2017, 2018 OraSure Technologies, Inc. • OraQuick®, logo design, and configuration are trademarks of OraSure Technologies, Inc. • (1) 610-882-1820

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