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

INSTRUCTIONS FOR USE

The OraQuick® HIV Self-Test is an *in-vitro* 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 to HIV-1 and HIV-2 from infected individuals. **You must follow the test directions carefully to get an accurate result.**

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. **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.**

VIEW INSTRUCTIONS
bit.ly/OQHIVSTenglish

VIEW INSTRUCTIONS
orasure.com

ENGLISH
SINGAPORE SIMPLIFIED CHINESE

ORAQUICK®
HIV SELF-TEST

HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT

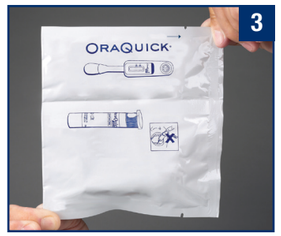
1

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.

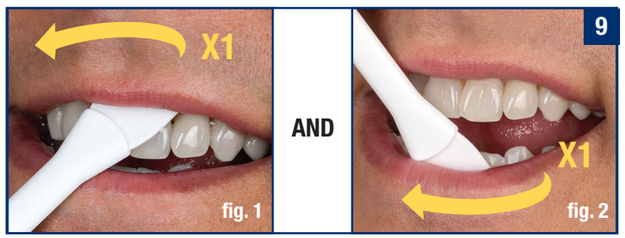
7

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

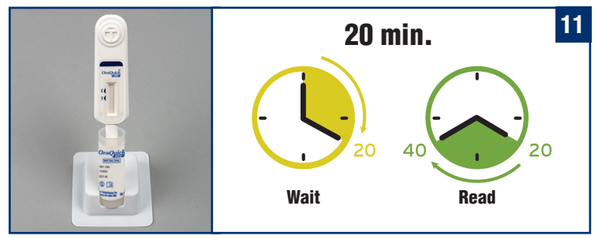


Press the **Flat Pad** firmly against your gum and swab it along your **upper gum once** (fig. 1) and **your lower gum once** (fig. 2).

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.

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 reported a negative test result. This is called a false negative.

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.

99.0% of people (717/724) correctly reported their result as negative. This means that 7 out of 724 people not infected with HIV reported a positive test result. This is called a false positive.

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.**

1.8% of study subjects (16 out of 900) failed to obtain a test result.

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.

PRODUCT INFORMATION

REF **5X4-1000, 5X4-1001, 5X4-2001**

WARNINGS AND PRECAUTIONS

- **DO NOT** use the test if you are HIV positive.
- **DO NOT** use the test if it has been exposed to household cleaning products (i.e. bleach).
- Remove dental products such as dentures or any other products that cover your gums prior to the oral fluid collection.
- 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 your health facility.
- **DO NOT** use if any of the package contents are missing, broken, or open.
- If today is after the ‘Use By’ on the outside of the pouch, do not use this test.

LIMITATIONS OF THE TEST

- Oral bleeding may result in an invalid result. If the test result is invalid, visit your nearest testing centre or healthcare facility.
- The OraQuick® HIV Self-Test may not detect HIV infections that have occurred within the last 3 months.
- For a positive result, the intensity of the test line does not necessarily equal the amount of antibody in the specimen.
- This product has not been evaluated for use in self-testing for individuals younger than 18 years of age.

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS

If you are HBV, HCV or HTLV (I/II) positive, you may get a false result. It is recommended that users observe a 15 minute wait period after food and drink and a 30 minute wait period after using oral care products.

EXPLANATION OF SYMBOLS

LOT	Batch Code	IVD	*In Vitro* Diagnostic Medical Device	0-2	Age Restriction	DOM	Date of Manufacturing
	Do Not Reuse		Use By		Consult Instructions for Use		
	Temperature Limitation		Caution, Consult Accompanying Documents	EXP	Date of Expiration		
REF	Catalog Number		Manufacture		Date of Manufacturing		

in Thailand for :

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