

Step 1. Collect Sample

Oral Fluid

Swab lower and upper gum **once**.
DO NOT swab the roof of the mouth, cheeks or tongue.



Go to Step 2

Fingerstick Whole Blood

Cleanse finger. Air dry.
Puncture with lancet.

Wipe away first drop of blood.
Fill the Collection Loop.



Venous Whole Blood

Validated for EDTA, sodium heparin and sodium citrate

Collect blood using standard
phlebotomy procedures.

Fill the collection Loop.

- Whole blood may be stored at 2-30°C (35-86°F) for up to 5 days.
- Invert the tube several times to mix.



Immediately insert the Loop into the Developer Solution. Mix.



Go to Step 2

Plasma

Validated for EDTA

Collect blood using standard
phlebotomy procedures.

Fill the Collection Loop.

- Centrifuge at 1000-1300 x g for approximately 5 minutes.
- Plasma may be stored up to 7 days at 2-8°C (35-46°F).
- Whole blood may be stored at 2-30°C (35-86°F) for up to 5 days.



Step 2. Perform the Test

Insert device into buffer.



Start the timer.



Pink fluid travels through the Result Window.



- Do NOT remove the device from the Developer Solution while the test is running.

Step 3. Read Results between 20 and 40 minutes

Non-reactive: Line in C Zone

Invalid: Repeat Test

Line in C Zone No HIV antibodies detected.	CDC recommendations for reporting HIV negative results: ¹	No Line in C Zone	Red background obscures results	Lines are outside of C or T Zones
	- HIV-negative test results may be conveyed without direct personal contact between the patient and the health-care provider. - Persons known to be at high risk for HIV infection also should be advised of the need for periodic retesting and should be offered prevention counseling or referred for prevention counseling.			

Reactive: Lines in C and T Zones. Report as preliminary positive. Order Western blot to confirm.

Examples of preliminary positive results. Line in C Zone in each test.	Line in T Zone.	Line in T Zone.	Faint line in T Zone	CDC recommendations ¹ reporting HIV positive results:
				- HIV positive test results should be communicated confidentially through person contact by a clinician, nurse, mid-level practitioner, counselor, or other skilled staff. - Active efforts are essential to ensure that HIV-infected patients receive their positive test results and linkage to clinical care, counseling, support and prevention services. - If the necessary expertise is not available in the health-care venue in which screening is performed, arrangements should be made to obtain necessary services from another provider, local health department, or community-based organization.

Performance Characteristics²

Multiple clinical studies were conducted to determine sensitivity and specificity of the OraQuick ADVANCE® HIV-1/2 Test. Confirmation was performed by a licensed Western blot, with confirmation of indeterminate results by IFA or radioimmunoprecipitation assay (RIPA).

Sensitivity

Specimen	Total Samples	OraQuick® Reactive	True Positive	OraQuick® Sensitivity	95% CI
Oral Fluid	3917	834	840	99.3%	98.4-99.7%
Fingerstick	1146	536	538	99.6%	98.5-99.9%
Plasma	1424	901	905	99.6%	98.9-99.8%

Specificity

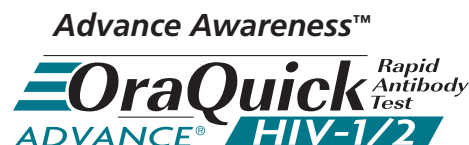
Total Samples	OraQuick® Non-reactive	True Negative	OraQuick® Specificity	95% CI
3755	3674	3682	99.8%	99.6-99.9%
1875	1856	1856	100.0%	99.7-100%
1636	1620	1622	99.9%	99.6-99.9%

Order Information

Description
Box of 25 tests
Box of 100 tests
Controls

Reimbursement Information

CPT Code
86703-92



OraSure Technologies

220 East First Street
Bethlehem, PA 18015 USA
phone: 800.ORASURE
web: www.OraSure.com
Made in the USA

1 Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, September 22, 2006/Vol. 55/No. RR-14.
2 OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Package Insert.

Please refer to the package insert for complete information and instructions on the proper use of the OraQuick ADVANCE® Rapid HIV-1/2 Antibody test. ©2009 OraSure Technologies, Inc. U.S. Patent #7,192,555 and various international and U.S. patents pending. OraQuick® and OraQuick ADVANCE® are registered trademarks of OraSure Technologies, Inc. Item# OQA0194 12/08