

# Detection is the first step in prevention

The CDC guidelines call for routine HIV screening<sup>1</sup>

## Objectives:

- Increase HIV screening of patients, including pregnant women.
- Detect HIV infection earlier in the disease state.
- Identify and counsel people with unrecognized HIV infection. The majority of people who are aware of their HIV infection substantially reduce risky behaviors to reduce further transmission.<sup>2</sup>
- Link HIV+ people to care to maximize the benefit of therapy.

**Risk-based testing is NOT reaching the goal of identifying all HIV+ people. The CDC guidelines recommends these steps to help stop the spread of HIV:**

- Screen all people 13-64 years old in all healthcare settings.
- Identify all HIV+ people. Connect them to care early.
- Educate people about risk factors to empower them to stay healthy.

## The OraQuick **ADVANCE**® HIV-1/2 Test is:

**Highly Accurate** >99% agreement with confirmatory Western blot.<sup>4</sup>

**Rapid** Reliable results in 20 minutes.

**Flexible** Only test approved by FDA for oral fluid, whole blood and plasma. Ideal for both point-of-care and laboratory settings.

Stop the spread of HIV one simple test at a time.

Advance Awareness™  
**OraQuick** Rapid  
Antibody Test  
**ADVANCE**® **HIV-1/2**



## Simple and Rapid Test Procedure for Oral Fluid or Fingertick Whole Blood\*

### 1 Collect sample

**Oral fluid:** Swab lower and upper gum once.

**Blood:** Fill the collection loop with fingertick whole blood. Mix with buffer.



### 2 Insert device into buffer.

### 3 Read between 20 and 40 minutes.

### Action steps with preliminary positive results:<sup>1</sup>



- Tell the person that they may be infected with HIV.
- Explain that the OraQuick® HIV-1/2 Test is a preliminary result.
- Order a Western blot confirmation.
- Educate the patient about risk factors and steps to avoid spreading HIV to others.
- Refer the person to a care provider.

\*CLIA waived for oral fluid, fingertick and venous whole blood. Moderately complex for plasma.

# Performance Evaluation of the OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 Test<sup>3</sup>

## Early Surveillance Study by CDC

### Overview

- Post-market surveillance in 368 sites affiliated with 17 state and city health departments.
- August 2004 to June 2005 (shortly after FDA approval).
- 135,724 whole blood samples and 26,066 oral fluid samples were tested.

### Objectives

- Monitor performance of the OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 Test with whole blood and oral fluid samples compared to confirmatory Western blot or IFA tests.
- Compare field performance with package insert claims for whole blood (100% CI 99.7-100%) and oral fluid (99.8% CI 99.6-99.9%).

## Results

Table 1. Summary for All Sites

	Seropositivity	Range	Specificity	Range	PPV	Range
Blood	0.83%	0.08-2.60%	99.98%	99.73-100%	99.24%	66.67-100%
Oral Fluid	1.00%	0.00-4.02%	99.89%	99.44-100%	90.00%	50.00-100%

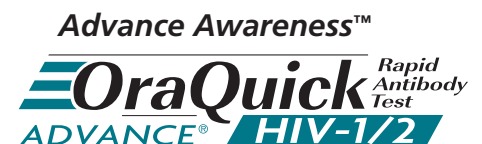
Table 2. True Positive (TP), False Positive (FP), Specificity and Positive Predictive Value (PPV) of the OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 Test

Health Department	Whole blood						Oral Fluid					
	OraQuick Negative	TP (%)	FP	Specificity	(95% CI)	PPV	OraQuick Negative	TP (%)	FP	Specificity	(95% CI)	PPV
Florida	24,635	651 (2.6%)	5	99.98%	(99.95–99.99)	99.2%	988	13 (1.3%)	1	99.90%	(99.44–100)	92.9%
New Jersey	20,707	392 (1.9%)	12	99.94%	(99.90–99.97)	97.0%	166	7 (4.0%)	0	100.00%	(97.80–100)	100.0%
New York State	16,199	72 (0.4%)	5	99.97%	(99.93–99.99)	93.5%	5,778	17 (0.3%)	14	99.76%	(99.60–99.87)	54.8%
New York City	13,673	199 (1.4%)	7	99.95%	(99.90–99.98)	96.6%	8,248	92 (1.1%)	11	99.87%	(99.76–99.93)	89.3%
Louisiana	11,784	179 (1.5%)	0	100.00%	(99.97–100)	100.0%	1,595	43 (2.6%)	3	99.81%	(99.45–99.96)	93.5%
Michigan	9,100	76 (0.8%)	0	100.00%	(99.96–100)	100.0%	72	1 (1.4%)	0	100.00%	(95.01–100)	100.0%
Delaware	7,364	50 (0.7%)	0	100.00%	(99.95–100)	100.0%						
Wisconsin	6,334	52 (0.8%)	4	99.94%	(99.84–99.98)	92.9%	691	6 (0.9%)	0	100.00%	(99.47–100)	100.0%
Indiana	4,868	37 (0.8%)	1	99.98%	(99.89–100)	97.4%	593	1 (0.2%)	1	99.83%	(99.50–100)	50.0%
Chicago	3,687	55 (1.5%)	1	99.97%	(99.85–100)	98.2%	2,018	15 (0.7%)	2	99.90%	(99.64–99.99)	88.2%
Arizona	3,549	83 (2.3%)	4	99.89%	(99.71–99.97)	95.4%	532	12 (2.2%)	3	99.44%	(98.37–99.88)	80.0%
San Francisco	3,474	93 (2.6%)	0	100.00%	(99.89–100)	100.0%	2,928	72 (2.4%)	8	99.73%	(99.46–99.88)	90.0%
Massachusetts	3,238	16 (0.5%)	0	100.00%	(99.89–100)	100.0%						
Utah	2,547	21 (0.8%)	0	100.00%	(99.86–100)	100.0%	1,558	14 (0.9%)	4	99.74%	(99.35–99.93)	77.8%
Montana	1,274	1 (0.1%)	0	100.00%	(99.71–100)	100.0%						
Nebraska	702	12 (1.7%)	0	100.00%	(99.48–100)	100.0%	219	1 (0.5%)	0	100.00%	(98.33–100)	100.0%
North Carolina	363	2 (0.6%)	1	99.73%	(98.48–99.99)	66.7%	299	0 (0.0%)	0	100.00%	(98.77–100)	n/a

## Conclusions

- This post-market surveillance study of the OraQuick *ADVANCE*<sup>®</sup> HIV-1/2 Test demonstrated high specificity with both whole blood and oral fluid. Performance was in accordance with manufacturer's claims and confirmed results from other independent studies.
- Specificity on oral fluid is slightly lower (99.89%) than that on whole blood (99.98%). However, oral fluid specimens may increase the number of people screened because non-medical professionals may be deployed in outreach and non-clinical settings.
- Given the low HIV seropositivity observed in some health department sites, the authors expected to find some low positive predictive values. The lower PPV for oral fluid compared to whole blood tests at some health departments "resulted primarily from fewer HIV infected persons who tested with oral fluid, rather than from lower specificity of the oral fluid test."

Order Information	Description	Reimbursement Information	CPT Code
	Box of 25 tests Box of 100 tests Controls		86703-92



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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 Meta-analysis of high risk sexual behavior in persons aware and unaware they are HIV infected in the US: Implications for HIV prevention programs Journal Acquired Immune Deficiency Syndrome 2005;39:446-453. 3 Post-marketing Surveillance of OraQuick Whole Blood and Oral Fluid Rapid HIV Testing, AIDS 2006 Vol 20 No 12 1661-1666. 4 OraQuick *ADVANCE*<sup>®</sup> 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*<sup>®</sup> 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<sup>®</sup> and OraQuick *ADVANCE*<sup>®</sup> are registered trademarks of OraSure Technologies, Inc. Item# OQA0193 12/08