

# Detection is the first step in prevention

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

## The Facts:

- More than 1.1 million people in the U.S. are infected with HIV and 232,700 don't know it<sup>2,3</sup>
- Women make up 26% of these infections.<sup>2</sup> 40-85% of infants infected with HIV are born to women whose HIV status is unknown at the time of delivery.<sup>3</sup>

**Risk-based testing is NOT reaching the goal of identifying all HIV+ people. The CDC guidelines recommend taking these steps to help stop the spread of HIV and prevent mother-to-child transmission:**

- CDC urges screening for all people 13-64 years old in all healthcare settings.<sup>1</sup>
- ACOG recommends screening as a routine part of gynecologic and obstetric care.<sup>4</sup>
- Repeat the HIV test in the third trimester in high HIV prevalence areas.<sup>1</sup>
- Screen all women without an HIV test record or high risk factors at time of delivery.<sup>1</sup>
- Begin antiretroviral prophylaxis without waiting for confirmatory results to minimize the chance of transmission to the infant.<sup>3</sup>

## The OraQuick ADVANCE<sup>®</sup> HIV-1/2 Test is:

**Highly Accurate** >99% agreement with confirmatory Western blot.<sup>6</sup>

**Rapid** Reliable results in 20 minutes.

**Flexible** Only test approved by FDA for oral fluid, whole blood and plasma. Ideal for both clinical and non-clinical settings.

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

Advance Awareness<sup>™</sup>  
**OraQuick** Rapid Antibody Test  
ADVANCE<sup>®</sup> 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 blood. Mix with buffer.



2 Insert device into buffer.



3 Read between 20 and 40 minutes.



Non-reactive.  
Line in the C Zone.



Preliminary positive.  
Lines in C and T Zones.

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

- Tell the woman she may have HIV infection.
- If pregnant, tell her that her baby may have been exposed and that the OraQuick<sup>®</sup> HIV-1/2 Test is a preliminary result.
- Order a Western blot confirmation.
- Initiate antiretroviral prophylaxis to reduce the risk of transmission to the infant.<sup>3</sup>
- Advise the woman to postpone breast feeding until the confirmatory results are available.<sup>3</sup>

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

# Mother-Infant Rapid Intervention at Delivery<sup>6</sup>

## Overview

### MIRIAD Study Overview

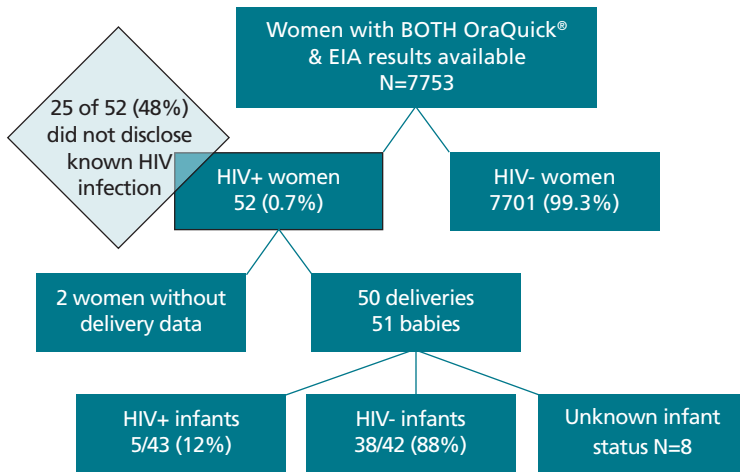
- Prospective, 16-center study funded by CDC.
- November 2001 to February 2005.
- Offered fingerstick OraQuick<sup>®</sup> HIV rapid testing to women with undocumented HIV status.
- Point-of-care and lab-based rapid test plus EIA.
- 7753 paired EIA and OraQuick<sup>®</sup> HIV tests.

### Objectives

- Determine feasibility of rapid HIV testing in L&D.
- Compare performance of the OraQuick<sup>®</sup> HIV test to EIA.
- Provide timely antiretroviral prophylaxis to reduce mother-to-child transmission.
- Facilitate follow-up care for HIV-infected women and their infants.

## Results

### Flow Chart of MIRIAD Participants



- 32 of 49 HIV+ women with delivery times were identified before delivery
- 2 of 43 with data on delivery and intrapartum prophylaxis received treatment.

### Estimated Positive Predictive Value of a Single HIV Screening Test in Populations with Differing HIV Prevalence<sup>3</sup>

HIV Prevalence	OraQuick <sup>®</sup> Blood*	Reveal Serum	Uni-Gold Blood	Single EIA†
10%	99%	92%	97%	98%
5%	98%	85%	95%	96%
2%	95%	69%	87%	91%
1%	91%	53%	77%	83%
0.5%	83%	36%	63%	71%
0.3%	75%	25%	50%	60%
0.1%	50%	10%	25%	33%
<b>Sensitivity</b>	100.0%	99.8%	100.0%	–
<b>Specificity</b>	99.9%	99.1%	99.7%	99.8%

\*Data for OraQuick<sup>®</sup> from MIRIAD study

†Calculations based on FDA-approved package inserts

### Sensitivity and Specificity<sup>7</sup>

OraQuick <sup>®</sup>	Western Blot		Total
	Positive	Negative	
Positive	52	6	58
Negative	0	7695	7695
<b>Total</b>	<b>52</b>	<b>7701</b>	<b>7753</b>

Sensitivity = 100% (CI = 93.15-100%)  
Specificity = 99.92% (CI = 99.83-99.97%)

PPV = 89.66% (CI = 78.83-96.11%)  
NPV = 100% (CI = 99.95-100%)

EIA	Western Blot		Total
	Positive	Negative	
Positive	52	18	70
Negative	0	7683	7683
<b>Total</b>	<b>52</b>	<b>7701</b>	<b>7753</b>

Sensitivity = 100% (CI = 93.15-100%)  
Specificity = 99.77% (CI = 99.63-99.86%)

PPV = 74.29% (CI = 62.44-83.99%)  
NPV = 100% (CI = 99.95-100%)

## Comments

- MIRIAD demonstrated that routine rapid HIV testing can be implemented intrapartum using a variety of models.
- In most settings, existing staff including nurses, midwives, OB/GYN residents and attending physicians implemented testing and counseling.
- The OraQuick<sup>®</sup> HIV test was performed at the point-of-care in the labor and delivery department or in the laboratory. The EIA test was performed in the laboratory only.
- HIV testing was accepted by 85% women, when offered.
- OraQuick<sup>®</sup> provided accurate and timely results. In the MIRIAD study, OraQuick<sup>®</sup> performed better than the EIA, with higher specificity and positive predictive value.

### Order Information

**Description**  
Box of 25 tests  
Box of 100 tests  
Controls

### Reimbursement Information

**CPT Code**  
86703-92

Advance Awareness<sup>™</sup>

**OraQuick<sup>®</sup>** Rapid Antibody Test  
**ADVANCE<sup>®</sup> HIV-1/2**

### OraSure Technologies

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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 Estimates of New HIV Infection in the United States, CDC HIV/AIDS Facts, August 2008. 3 ACOG Committee Opinion, Number 304, November 2004. 4 ACOG Committee Opinion Number 411, Routine HIV Screening Obstetrics & Gynecology Vol. 112/No. 2, August 2008. 5 OraQuick ADVANCE<sup>®</sup> Rapid HIV-1/2 Antibody Test Package Insert. 6 American Journal of Obstetrics and Gynecology, Supplement to September 2007, 572-5-82. 7 American Journal of Obstetrics and Gynecology, Supplement to September 2007, 580 Table 4.

Made in the USA

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# OQA0189 12/08