

# THE NCCC BULLETIN

## From the Editors

Rapid HIV testing, which provides results in minutes, can simplify and expand the availability of HIV testing. Three rapid HIV tests approved by the U.S. Food and Drug Administration (FDA) are available commercially in the United States:\* (1) OraQuick Rapid HIV Antibody Test; (2) Reveal G-2 Rapid HIV-1 Antibody Test; and (3) Uni-Gold Recombigen HIV-1 Test. Prior to the FDA approval of these 3 tests, the most commonly used rapid HIV test was the Single-Use Diagnostic System (SUDS) test, which is no longer available.

Rapid HIV tests are screening tests, and any positive result therefore must be followed up with a confirmatory test (Western blot or immunofluorescent antibody). Rapid HIV testing has a key role in the "Advancing HIV Prevention" program of the Centers for Disease Control and Prevention (CDC). In addition, these tests can be extremely useful in situations when immediate information about HIV status is desirable, e.g., when testing the source patient before initiat-

ing postexposure prophylaxis or at delivery for women who have not been tested recently for HIV.

The National HIV/AIDS Clinicians' Consultation Center (NCCC) has a dedicated line for answering questions about rapid HIV testing in pregnancy and the care of HIV-infected pregnant patients. The **Perinatal Hotline** at **888-448-8765**, which is an extension of the NCCC's Warmline and PEpline services, is available 24 hours a day for emergency and routine consultations.

We recently received the following question from a nurse practitioner regarding rapid testing.

### Question:

"Is the new rapid HIV test reliable and how does it compare to the SUDS rapid HIV test?"

### Response:

In order to present a clearer comparison of the various rapid HIV tests, tables 1 and 2 were faxed to the caller. The comments that follow were discussed with the caller.

**Table 1: Characteristics of the Rapid Tests<sup>1,2,3</sup>**

	OraQuick Rapid	OraQuick Advance Rapid	Reveal G-2 Rapid	Uni-Gold Recombigen
<b>Tests for:</b>	HIV-1	HIV-1 and HIV-2	HIV-1	HIV-1
<b>Sample</b>	Whole blood Plasma	Whole blood Plasma Oral fluid	Serum Plasma	Whole blood Serum Plasma
<b>CLIA waived?<sup>i</sup></b>	Whole blood: yes Plasma: no	Whole blood, oral fluid: yes Plasma: no	No	Whole blood: yes Serum, plasma: no
<b>Sensitivity (%)<sup>ii</sup></b>	99.6	Whole blood, plasma: 99.6 Oral fluid: 99.3	99.8	100
<b>Specificity (%)<sup>iii</sup></b>	Whole blood: 100 Plasma: 99.9	Whole blood: 100 Plasma, oral fluid: 99.9	Serum: 99.1 Plasma: 98.6	99.7-99.9
<b>Time to result</b>	20-40 min.	20-40 min.	3-30 min.	10 min.
<b>Comment</b>	This test probably will be phased out and replaced by the OraQuick Advance Rapid HIV-1/2 Antibody Test.	Using oral fluid may help to decrease percutaneous exposures.		

<sup>i</sup> CLIA (Clinical Laboratory Improvement Amendments of 1988) waived, which means that there are fewer federal restrictions on who can perform the test (personnel and professional requirements waived) and on where this test can be performed (lab site inspection waived).

<sup>ii</sup> Sensitivity: percentage of those who have the disease who test positive.

<sup>iii</sup> Specificity: percentage of those who do not have the disease who test negative.

**Note:** The traditional EIA/ELISA HIV antibody test has a sensitivity of 100% and a specificity of 99.8%.

- In addition to knowing the sensitivity and specificity of a test, it is important to know the positive predictive value of a test, which is the probability that a positive test result indicates a true infection. Positive predictive values depend on the disease prevalence in a given population. Comparisons of the positive predictive values of the 3 approved rapid HIV tests, the SUDS test, and the traditional enzyme-linked immunosorbent assay (ELISA or EIA) HIV test are provided in the table below.<sup>1,3</sup>

**Table 2: Estimated Positive Predictive Value**

Disease Prevalence (%)	OraQuick (whole blood)	OraQuick (plasma)	Reveal (serum)	UniGold (whole blood)	Single EIA	SUDS (serum)
10	100	99	92	97	98	96
5	100	98	85	95	96	91
2	100	95	69	87	91	80
1	100	91	53	77	83	67
0.5	100	83	36	63	71	50
0.3	100	75	25	50	60	38
0.1	100	50	10	25	33	18
<b>Specificity (%)</b>	100	99.9	99.1	99.7	99.8	99.6

**Note:** The SUDS test has a sensitivity of 99.9-100% and a specificity of 99.6-99.7%.

- Key points that can be derived from the above tables are:
  - o All approved rapid HIV tests are very reliable. Any HIV test, however, may fail to detect infection in individuals who were exposed to HIV <3 months prior to being tested (window period).
  - o The occurrence of false positive results is much less frequent with the OraQuick Rapid Test than with the other rapid tests and the traditional EIA test.
  - o Due to OraQuick’s CLIA-waived status, its accuracy, and its use on oral fluid for detecting both HIV-1 and HIV-2, it will probably become the most commonly used test.
- There are 3 important contexts in which rapid HIV testing may have a major role:

1) *Providing opportunity for more widespread and effective HIV testing (especially with tests that are CLIA waived)*

It is estimated that about 900,000 persons in the United States are infected with HIV.<sup>4</sup> Approximately 225,000 of these persons are unaware of their HIV status.<sup>5</sup> In 2001, the CDC launched a new strategy for HIV prevention called the Serostatus Approach to Fighting the Epidemic (SAFE).<sup>6</sup> One of the goals of this strategy is to reduce new HIV infections in the United States by 50% by the year 2005. To reach this goal, it is estimated that 30,000 individuals each year must become aware of their HIV status and then be linked to appropriate care and preventive services. However, with the current standard EIA test, approximately 25% of those who have a positive test do not return to get their results.<sup>5</sup> Rapid HIV testing could decrease the scale of this problem; in settings where rapid testing is offered, early data indicate that many individuals who are told they are preliminarily positive at the time of the rapid test do return for the confirmatory test.<sup>7,8</sup> One concern about rapid HIV testing is that the emphasis on speed may reduce the time for pretest and posttest counseling.

2) *Postexposure prophylaxis*

The CDC’s “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis,” issued June 29, 2001, states: “An FDA approved rapid HIV antibody test kit should be considered for use in this situation, particularly if testing by EIA cannot be completed within 24-48 hours.” Negative rapid HIV tests on source patients immediately can help to decrease anxiety in exposed individuals and decrease the use of empirical postexposure prophylaxis.

### 3) Testing women whose HIV status is unknown at the time of labor and delivery

Offering rapid HIV testing to women whose HIV status is not known at the time of labor and delivery affords the opportunity to reduce vertical transmission, even among women who do not receive prenatal care until labor begins. The CDC-sponsored Mother-Infant Rapid Intervention at Delivery (MIRIAD) study<sup>9</sup> showed that offering voluntary testing with the OraQuick HIV Antibody Test to women whose HIV status was unknown at the time of labor and delivery provided accurate and timely results:

- The study involved 4,849 pregnant women (inclusion criteria: no prenatal HIV testing, active labor, at  $\geq 24$  weeks' gestation or, if not in active labor, presenting at  $\geq 34$  weeks' gestation), 34 women tested positive for HIV on rapid test and EIA with results confirmed by Western blot. HIV prevalence in this study group was 0.7%.
- There were 4 false positives on the rapid test and 11 false positives on the standard EIA.
- For the OraQuick rapid test in this study, the sensitivity was 100%, the specificity was 99.9%, and the positive predictive value was 90%.
- For the standard EIA, the sensitivity was 100%, the specificity was 99.8%, and the positive predictive value was 76%.

For more information on rapid HIV testing, see the CDC resources at: [http://www.cdc.gov/hiv/rapid\\_testing/](http://www.cdc.gov/hiv/rapid_testing/).

*\* Note: On November 12, 2004, the FDA approved a new rapid HIV test, the Multispot HIV-1/HIV-2 Rapid Test. The test is done on plasma and serum and will not be CLIA waived. The sensitivity using serum or plasma for HIV-1/2 is 100%. The specificity using serum for HIV-1/2 is 99.93% and using plasma is 99.91%. For more information on this rapid test, visit the FDA Web site at: <http://www.fda.gov/cber/pmasumm/P040046S.pdf>.*

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National HIV Telephone Consultation Service  
(Warmline) 800/933-3413

National Clinicians' Post-Exposure Prophylaxis Hotline  
(PEpline) 888/448-4911

National Perinatal HIV Consultation and Referral Service  
(Perinatal Hotline) 888/448-8765

#### *The NCCC Bulletin*

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