HIV Rapid Tests: Progress, Perspective, and Future Directions

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In November 2002, the U.S. Food and Drug Administration approved the OraQuick® Rapid HIV-1 Antibody Test (OraSure Technologies, Inc., Bethlehem, PA), a reliable, rapid test that detects HIV-1 antibodies. In contrast to other HIV-testing techniques, the OraQuick test uses blood obtained by finger stick instead of venipuncture and provides results in 20 minutes. Implications for practice, as well as future applications of this technology, are discussed in this article.

Key Words: HIV, HIV antibodies, anonymous testing

The Centers for Disease Control and Prevention (CDC, 2002) estimated that of the 900,000 HIV-infected individuals in the United States, 225,000 do not know that they are infected. In addition, each year, approximately 8,000 people are HIV-tested and do not return for results (U.S. Food and Drug Administration [FDA], 2002). The FDA recently approved an HIV-1 rapid test method that hopefully will impact barriers to HIV testing and thus facilitate HIV testing and thus facilitate

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The approval of the OraQuick® Rapid HIV-1 Antibody Test (OraSure Technologies, Inc., Bethlehem, PA) was announced in November 2002 (FDA, 2002). However, this test is not approved for screening blood donors. The test is reliable (i.e., 99.6% accurate) in rapidly detecting HIV-1 antibodies, and results are available within 20 minutes (FDA: Salgado, Flanagan, Haverstick, & Farr, 2002).

Test Administration

The OraQuick test is designated as “moderate complexity” under the Clinical Laboratory Improvements Amendments (CLIA) of 1988 (FDA, 2002). This designation indicates that this test can only be given in CLIA-approved laboratories by CLIA-certified laboratory technicians or medical staff. However, if the manufacturer applies for and receives a CLIA waiver, the test could be used in additional healthcare settings (e.g., HIV-counseling centers) and potentially could be administered by other credentialed individuals, such as social workers practicing in counseling centers (see Figure 1). A CLIA waiver would indicate that after additional evaluation, the FDA finds that test data show that the OraQuick test is easy and safe to use (FDA).

The CDC (2002) advised that individual states may have more specific and additional requirements besides those of the FDA.

The Abbott Murex Single Use Diagnostic System for HIV (SUDS) (Abbott Diagnostics, Irving, TX) is another rapid HIV-1 test that is available and has been approved by the FDA with a moderate complexity rating. This test differs from the OraQuick test in that the SUDS requires serum or plasma serum samples that are obtained by venipuncture.

The OraQuick test uses whole blood, which can be obtained by finger stick (CDC, 2002). The blood sample is collected on a device similar to a dipstick and then placed in a vial containing a developing solution. A positive result for HIV-1 antibodies is indicated by the display of two reddish-purple lines on the vial. Reactivity requires confirmation with immunofluorescence assay or Western Blot. Because of the predictive value of negative screening results, negative results do not require additional confirmation and can be provided at the time of testing and counseling (CDC, 2002).

Counseling Considerations

The CDC (2002) recommended that patients who are nonreactive but who may have been exposed within three months to HIV should be retested to provide for sufficient time for detectable antibodies to develop. The CDC (2002) noted that “persons whose rapid-test results are reactive should be counseled about their likelihood of being infected with HIV and precautions to prevent HIV transmission, but they should return for definitive test results before medical referrals or partner counseling is initiated.” The same standards should be used to guide the conduct of counseling and testing. The counseling, testing, and referral (CTR) guidelines, according to the CDC (2001), are as follows.

- Protect the confidentiality of clients who are recommended or receive HIV CTR services.
- Obtain informed consent before performing an HIV test.
- Provide clients with the option of anonymous HIV testing.
- Provide information regarding the HIV test to all who are recommended and to all whether prevention counseling is provided or not.
- Adhere to local, state, and federal regulations and policies that govern the provision of HIV services.
- Provide services that are responsive to client and community needs and priorities.
- Provide services that are appropriate to the client’s culture, language, sex, sexual orientation, etc.
- Ensure high-quality services.

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