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Supplemental Testing for Confirmation of Reactive Oral Fluid Rapid HIV Antibody Tests

In March 2004, the Food and Drug Administration (FDA) approved the OraQuick® Rapid HIV-1 Antibody Test (OraSure Technologies, Bethlehem, Pennsylvania) for use with oral fluid by trained personnel as a point-of-care test to aid in the diagnosis of infection with human immunodeficiency virus (HIV). In June 2004, FDA approved an added claim for detection of HIV-2 antibodies in oral fluid and a change in the name of the device to OraQuick® Advance Rapid HIV-1/2 Antibody Test.

A reactive rapid HIV test result is considered preliminary and must be confirmed by supplemental testing (*1*). Some false positive rapid test results (i.e., reactive rapid test results followed by negative supplemental test results) are to be expected within the range of specificity for the device. However, in late 2005, HIV testing programs in multiple U.S. cities experienced apparent clusters of false-positive rapid HIV test results using oral fluid (but not whole blood) specimens. Counselors at these programs have expressed concern regarding the specificity and positive predictive value of the oral fluid rapid HIV test. The published sensitivity and specificity for the test using oral fluid are 99.3% (95% confidence interval [CI] = 98.4%–99.7%) and 99.8% (CI = 99.6%–99.9%), respectively. CDC has received multiple inquiries concerning whether its guidelines for confirmatory testing for reactive rapid HIV tests on oral fluid specimens have been modified.

CDC is actively working with FDA, state and local health officials, and the product manufacturer to investigate these reports, assess the test's current performance, and consider whether changes in testing protocols should be recommended or any other actions taken. In the meantime, current protocols for confirmation of reactive rapid HIV test results should continue to be followed (*2*). These protocols ensure that clients with reactive rapid test results receive accurate HIV test results after confirmation. HIV counselors returning reactive (preliminary positive) results from HIV rapid tests to clients should provide the same counseling message that is currently recommended (*3*), regardless of whether the reactive test result was obtained using oral fluid or whole blood. HIV testing program directors who have noted any problems or who have concerns over the performance of the OraQuick Advance Rapid HIV-1/2 Antibody Test in their particular settings should report these concerns to OraSure Technologies at telephone 800-672-7873.

References

1. CDC. Quality assurance guidelines for testing using the OraQuick® Rapid HIV-1 Antibody Test. Atlanta, GA: US Department of Health and Human Services, CDC; 2003. Available at http://www.cdc.gov/hiv/rapid_testing/materials/qa_guidlines_oraquick.pdf.
2. CDC. Notice to readers: protocols for confirmation of reactive rapid HIV tests. MMWR 2004;53:221–2.
3. CDC. HIV counseling with rapid tests. Atlanta, GA: US Department of Health and Human Services, CDC; 2003. Available at http://www.cdc.gov/hiv/pubs/rt-counseling.htm.

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