Reports of false positive oral rapid test results

On December 16th, 2005, The Centers for Disease Control and Prevention (CDC) issued an MMWR Dispatch regarding recent reports of a higher than expected number of false positive test results in certain geographic areas using the oral fluid rapid test for HIV. The Dispatch is available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm54d1216a1.htm

The following information is intended to address questions related to the reports of false positive results reported in the MMWR Dispatch:

- CDC, in cooperation with FDA, reminds users of rapid HIV tests that *all* preliminary positive test results *must* be confirmed with additional more specific tests in a manner consistent with previously published guidance. (see http://www.cdc.gov/hiv/rapid_testing/materials/qa_guidlines_oraquick.pdf)
- FDA is aware of recent reports of an unexpected increase in false positive results for the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test with oral fluid specimens mainly at testing sites in New York City and San Francisco.
- When whole blood specimens were used for testing, there was no observed increase in the false positive rate of this test at these test sites.
- Some false positive test results are expected with any HIV screening test. For this reason additional testing is always needed to confirm true positive results.
- The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test for use with oral fluid specimens was approved in June 2004 with a reported sensitivity of 99.6% and a specificity of 99.8% based on clinical studies.
- A specificity of 99.8% means that users should expect approximately 2 false positive results out of every 1,000 tests. However, the reported rate of false positive test results has been as high as 9 per thousand in recent months at some locations.
- FDA believes that use of a rapid HIV test on oral fluid can continue as long as test subjects are properly informed about the need for additional testing to confirm or reject preliminary positive results on the rapid screening test.
- FDA is working closely with the manufacturer of OraQuick (OraSure Technologies, Bethlehem Pennsylvania), the Centers for Disease Control and Prevention (CDC), and local departments of public health to determine the nature and cause of these findings and will take further actions if needed.

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