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FDA Approves First Oral Fluid Based Rapid HIV Test Kit

FDA today approved the use of oral fluid samples with a rapid HIV diagnostic test kit that provides screening results with over 99 percent accuracy in as little as 20 minutes. Until now, all rapid HIV tests required the use of blood in order to get such rapid results.

The original version of this rapid test -- the OraQuick Rapid HIV-1/2 Antibody Test, manufactured by OraSure Technologies, Inc., Bethlehem , Pa. -- was approved November 7, 2002 for detection of antibody to HIV-1 in blood. On March 19, 2004 , FDA approved the test for detection of HIV-2 (a variant of HIV that is prevalent in parts of Africa but rarely found in the United States) in blood. Today's approval represents another significant new use for the test. As when used on blood, this test can quickly and reliably detect antibodies to HIV-1 and can be stored at room temperature and requires no specialized equipment.

"Before the approval of this rapid test in November, 2002, many people being tested for HIV in public clinics did not return for the results of standard tests," said HHS Secretary Tommy G. Thompson. "Where the rapid test is available, those tested get their results within minutes. This oral test provides another important option for people who might be afraid of a blood test. It will improve care for these people and improve the public health as well."

To perform the test, the person being tested for HIV-1 takes the device, which has an exposed absorbent pad at one end, and places the pad above the teeth and against the outer gum. The person then gently swabs completely around the outer gums, both upper and lower, one time around. The tester then takes the device and inserts it into a vial containing a solution. In as little as 20 minutes, the test device will indicate if HIV-1 antibodies are present in the solution by displaying two reddish-purple lines in a small window on the device.

Although the results of rapid screenings will be reported in point-of-care settings, as with all screening tests for HIV, if the OraQuick test gives a reactive test result, that result must be confirmed with an additional more specific test. The OraQuick test has not been approved to screen blood donors. Although the test is approved to detect antibodies to HIV-1 and –2 when used on blood, today’s approval of the test for use on oral fluid is limited to detection of antibodies to HIV-1.

The OraQuick Rapid HIV-1/2 Antibody test for use on blood was categorized as a waived test under CLIA (Clinical Laboratory Improvements Amendments of 1988) in January, 2003. A waived test system can be given in facilities with any CLIA certificate, rather than only in facilities certified for higher complexity tests. As such, a test categorized as a waived test can be used in many more health care settings by many different health providers.

All new test systems are categorized as high complexity systems until they are submitted for categorization under CLIA.

"I strongly urge the OraSure company to apply for a CLIA waiver for this test using oral fluid samples as well," said Acting FDA Commissioner Lester M. Crawford, D.V.M., Ph.D. "If the FDA finds that the company’s data proves that the OraQuick test used with oral fluids is both easy and safe to use in the waived lab setting - as it is with used with blood - then more people will likely be

tested for HIV infection. In addition, any risk to healthcare workers of performing the test will be greatly reduced since they will not be exposed to blood."

The Centers for Disease Control and Prevention (CDC) has estimated that one fourth of the approximately 900,000 HIV-infected people in the U.S. are not aware that they are infected. Because of the potential public health benefits of rapid HIV testing, the CDC and the Centers for Medicare and Medicaid Services (CMS) have worked with state and other health officials to make the test widely available and to offer technical assistance and training for its use.

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