FDA Approves In-Home, Do-It-Yourself Rapid HIV Test

July 3, 2012 By Tim Horn

OraSure's OraQuick In-Home HIV Test, the first do-it-yourself HIV test kit to detect the presence of antibodies to HIV, has been approved by the U.S. Food and Drug Administration, according to news announcements by the company and the agency. It is the first rapid diagnostic test for any infectious disease to be approved by the FDA for sale over the counter.

According to OraSure, the test will be available for purchase this October at more than 30,000 retail outlets throughout the country and online. Though its price has not be disclosed, the company announced on a July 3 conference call with investors that it would cost "slightly more" than the $17.50 currently be charged for the oral-based rapid assay used by professionals.

"Approval of the OraQuick In-Home HIV Test represents a major breakthrough in HIV testing," said Douglas A. Michels, president and chief executive officer of OraSure Technologies. "For the first time ever, individuals will have access to an in-home oral test that will empower them to learn their HIV status in the comfort of their home and obtain referral to care if needed. This new in-home rapid test—the same test doctors have used for years—will help individuals at risk for HIV who otherwise may not test in a professional or clinical setting."

The test is designed to allow individuals to collect an oral fluid sample by swabbing the upper and lower gums inside their mouths. The sample is then placed into a developer vial, with results available within 20 to 40 minutes.

A positive result with this test does not mean that an individual is definitely infected with HIV, the FDA stresses, but rather that additional testing should be done in a medical setting to confirm the test result.

Similarly, a negative test result does not mean that an individual is definitely not infected with HIV, particularly when exposure may have been within the previous three months.

Clinical studies for self-testing have shown that the OraQuick In-Home HIV Test has an expected performance of 92 percent for test sensitivity, the percentage of results that will be positive when HIV is present. This means that one false negative result would be expected out of every 12 test results in people who are actually HIV positive.

Clinical studies also have shown that the OraQuick In-Home HIV Test has an expected performance of 99.98 percent for test specificity, the percentage of results that will be negative when HIV is not present. This means that one false positive would be expected out of every 5,000 test results in people who are actually HIV negative.

Once the in-home test is available to the public, OraSure will have a consumer support center that is available via phone 24 hours a day, seven days a week. The center will educate users with information about HIV/AIDS, the proper method for administering the test and guidance on what to do once results have been obtained. Information about the consumer support center and contact information is included in the test kit.

When used correctly, the test has the potential to identify large numbers of previously undiagnosed HIV infections, especially if used by those unlikely to use standard screening methods.

“Knowing your status is an important factor in the effort to prevent the spread of HIV,” said Karen Midthun, MD, director of the FDA’s Center for Biologics Evaluation and Research. “The availability of a home-use HIV test kit provides another option for individuals to get tested so that they can seek medical care, if appropriate.”

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