FDA NEWS RELEASE

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FDA approves first over-the-counter home use HIV test kit

The U.S. Food and Drug Administration today approved the OraQuick In-Home HIV Test, the first over-the-counter, self-administered HIV test kit to detect the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2). HIV is the virus that causes acquired immune deficiency syndrome (AIDS).

The OraQuick In-Home HIV Test is designed to allow individuals to collect an oral fluid sample by swabbing the upper and lower gums inside of their mouths, then place that sample into a developer vial, and obtain test results within 20 to 40 minutes. A positive result with this test does not mean that an individual is definitely infected with HIV, 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. 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.

The Centers for Disease Control and Prevention estimates that 1.2 million people in the United States are living with HIV infection. About one in five are not aware they are infected. There are about 50,000 new HIV infections every year. Many of these new infections are transmitted from people who are unaware of their HIV status.

“Knowing your status is an important factor in the effort to prevent the spread of HIV,” said Karen Midthun, M.D., 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.”

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 HIV-infected individuals.

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 uninfected individuals.

OraSure Technologies, the manufacturer of the OraQuick In-Home HIV Test will have a consumer support center that is available via phone and will be open 24 hours a day, seven days a week. The

center will be operational and available to 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 once the manufacturer makes the product available for sale to the public. Information about the consumer support center and contact information is included in the test kit.

OraSure Technologies, Inc. is headquartered in Bethlehem, Pa. A version of this test for use by trained technicians in clinical settings was approved in 2004.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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