

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

By GoPride.com News Staff July 3, 2012

http://chicago.gopride.com/news/article.cfm/articleid/30892500

Clinical study shows false negative in one out of every 12 test results

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.

The OraQuick In-Home HIV Test allows 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.

The FDA cautioned that 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.

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," Karen Midthun, M.D., director of the FDA's Center for Biologics Evaluation and Research, said in a statement. "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 have shown that one false negative result would be expected out of every 12 test results in HIV-infected individuals. Clinical studies also show 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.

Information from FDA press release