

US approves 1st rapid, take-home HIV test (Update)

July 3 2012, by MATTHEW PERRONE



In this undated handout photo provided by Orasure a model demonstrates the OraQuick test, which detects the presence of HIV in saliva collected using a mouth swab. The test is designed to return a result within 20 to 40 minutes. The U.S. Food and Drug Administration approved the first over-the-counter HIV test Tuesday, July 3, 2012, allowing Americans to check themselves for the virus that causes AIDS in the privacy of their homes. (AP Photo/Orasure, Chuck Zovko)

The U.S. Food and Drug Administration has approved the first over-the-counter HIV test, allowing Americans to check themselves for the virus that causes AIDS in the privacy of their homes.

The OraQuick test detects the presence of HIV in saliva collected using a mouth swab. The test is designed to return a result within 20 to 40 minutes.

Government officials estimate one-fifth, or about 240,000 people, of the 1.2 million HIV carriers in the U.S. are not aware they are infected. Testing is one of the chief means of slowing new infections, which have held steady at about 50,000 per year for two decades.

FDA officials said the test is aimed at people who might not otherwise get tested. The company's marketing efforts will focus on populations at greatest risk of being infected, including gay and bisexual men, African Americans and Hispanics.

HIV awareness groups hailed the approval as an important step in expanding testing for the virus.

"This test will allow anyone to empower themselves to know their HIV status when, how and with whom they want to," said Tom Donohue, founding director of Who's Positive.



This undated handout photo provided by Orasure shows the OraQuick test, which detects the presence of HIV in saliva collected using a mouth swab. The test is designed to return a result within 20 to 40 minutes. The U.S. Food and Drug Administration approved the first over-the-counter HIV test Tuesday, July 3, 2012, allowing Americans to check themselves for the virus that causes AIDS in the privacy of their homes. (AP Photo/Orasure, Chuck Zovko)

HIV eventually develops into AIDS, unless treated with antiviral drugs. AIDS causes the body's immune system to break down, leading to infections which become fatal.

The FDA previously approved several HIV test kits designed to be used at home, although those kits — which usually require a blood sample — must be sent to a laboratory to be developed.

FDA stressed in its approval announcement that the test is not 100 percent accurate.

A trial conducted by Orasure showed the home test correctly detected HIV in those carrying the virus only 92 percent of the time. That means the test could miss one person for every 12 HIV-infected people who use the kit.

The test was accurate 99 percent in ruling out HIV in patients not carrying the virus. That means the test would incorrectly identify one patient as having HIV for every 5,000 HIV-negative people tested.

People who test negative should get re-tested after three months because it can take several weeks for detectable antibodies to HIV to appear, according to Dr. Jonathan Mermin, director of the Centers for Disease Control and Prevention's HIV unit.

Orasure has marketed a version of OraQuick to doctors, nurses and other health care practitioners since 2002. When used by professionals, the test is shown to accurately identify both carriers and non-carriers 99 percent of the time.

While it's not clear why the test appears less accurate in consumer trials,

company researchers said they expected the test's specificity to drop when used by consumers versus professionals.

Orasure plans to launch the test in October, selling it through retailers like Walgreens, CVS and Walmart, as well as online pharmacies.

Whereas the test marketed to health professionals costs about \$17.50, Orasure expects the consumer version to sell for more. The company is not announcing a price yet, but said it would be less than \$60. CEO Doug Michels said the additional cost will help pay for a toll-free call center to provide counseling and medical referrals to test users.

Shares of Orasure Technologies rose 59 cents, or 5 percent, to \$12.09.

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