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## PROFESSION

### FDA approves in-home HIV test that gives results within an hour

The test requires confirmatory lab testing, so patients may contact their physicians for follow-up if they test positive.

By **KEVIN B. O'REILLY**, amednews staff. *Posted July 25, 2012.*

It takes between 20 and 40 minutes for the OraQuick In-Home HIV Test to deliver results on whether a person is HIV positive, but it took seven years for the test to win Food and Drug Administration approval for over-the-counter sales to patients.

FDA officials required the product's manufacturer, OraSure Technologies, to conduct studies to prove that patients could reliably follow written instructions to use the test, interpret the results and access follow-up care. In July, OraSure won FDA approval ([fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm310436.htm](http://fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm310436.htm)).

"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 an over-the-counter, home-use, rapid HIV test kit provides another option for individuals to get tested so that they can seek medical care, if appropriate."

The Centers for Disease Control and Prevention estimates that 20% of U.S. patients infected with HIV do not know their status. That is about 240,000 Americans.

The in-home test could help patients overcome barriers to testing and reduce the spread of HIV, said Ron Ticho, senior vice president of corporate communications at Bethlehem, Pa.-based OraSure.

"We recognize that this in-home option for testing isn't necessarily for everyone," Ticho said. "Some patients will come to a physician's office and ask to get tested, and would prefer being tested in the presence of a health care professional. However, we know that there are many individuals who perhaps would prefer to do testing in the privacy of their own home. And if physicians have patients who feel that way, they'll be able to recommend this option."

#### Following up by phone

OraSure will provide round-the-clock telephone support through a toll-free number listed on the packaging to help patients administer and interpret the test and get follow-up care, if needed. Each support staffer will receive 160 hours of training, company officials said. During business hours, they will stay on the line with callers until they are connected to a physician's office or other treatment center.

Sale of the product will be restricted to patients 17 and older. It will be available in more than 30,000 retail locations, such as Walgreens and Rite Aid, starting in October. No suggested retail price has been announced.

The OraQuick test, which can detect HIV antibodies, is administered by swabbing the gums and inserting the vial into a solution. About one in 5,000 tests will result in a false positive, the FDA said.

Test results will need to be confirmed through laboratory testing. One in every 12 OraQuick tests yields a false negative. Also, the test does not reliably detect HIV until at least three months after the infection.

Before approval, some physicians, HIV specialists and public health experts voiced concerns about the test's rate of false negatives and the possibility that patients who test positive may fail to seek vital follow-up treatment and counseling. In 2006, the CDC recommended that all patients be screened for HIV on a routine basis. Numerous studies have found that physicians and hospitals are not always following that guideline, and that many patients refuse to be tested when they are asked.



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