



# Coming soon: over-the-counter oral AIDS test

FDA weighs retail sales of cheap, quick HIV test by Pennsylvania firm. Easy access could be positive for public health, but researchers at Columbia identify possible negative impacts on behavior.

By Gale Scott  
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Safe sex could get safer.

With HIV infection remaining a major health concern in New York City, many public health researchers are clamoring for an over-the-counter oral test for the virus. The thinking is that a home kit would let people test themselves, or to insist that partners or potential partners take and pass the test as a condition of having unprotected sex.

That test could arrive soon, if the FDA rules favorably on an application from OraSure Technologies. The Bethlehem, Penn., company has asked permission to have its OraQuick rapid HIV test approved for retail sale—much like a home pregnancy test. The product is widely used in clinical settings and is expected to sell for around \$20 if approved.

Though many companies sell rapid HIV tests, OraSure is the only one that sells both blood and oral tests. Six others sell blood tests. "Our market share is 70% to 80% in public health and 50% to 60% in hospitals. We are the market leader" said OraSure CEO Douglas Michels.

FDA approval could come this year, ending a process that started when the company approached the FDA in 2004 with market research that showed a \$500 million potential U.S. sales-demand for a home test. The company submitted its final module of clinical tests results to the FDA in last month.

Physically, the process would be simple: wipe a swab inside the mouth, dip it into a container, wait 20 minutes. One line means HIV negative, two lines means it is positive. In terms of manners however, it would be anything but simple, according to a study by Columbia University researchers published Wednesday.

Alex Carballo-Diéguez, Timothy Frasca and colleagues at the HIV Center for Clinical and Behavioral Studies at the New York State Psychiatric Institute recruited subjects from a high-risk group, men who have sex with men. Though the HIV test would be marketed to heterosexuals as well, the researchers chose homosexual and bisexual men because the virus is spreading more quickly in that demographic. Of 3,481 new HIV diagnoses in New York City in 2010, 52.1% were among these men, versus 47.4% in 2009, according to the New York City Department of Health and Mental Hygiene.

In the Columbia study, researchers offered these men the OraQuick test in their office and then interviewed them about their attitudes toward using it. Most—over 80% of the men—said they would use the kit to test sexual partners or themselves if it became available over the counter.

But there was little agreement on how to broach the subject with a partner, how to handle an unexpected positive result, or deal with other situations. "The most surprising thing was how people would use it," said Mr. Carballo-Diéguez, "Some people said they would use it with casual partners, others said they would want there to be familiarity, and would use it only with their main partner."

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The study, published in the *Journal of Sex Research*, included remarks and explanations from the test subjects, identified only by age and ethnicity.

Asked how they would bring up the topic of taking the test, some said they would be blunt and direct. The study quoted a Latino man, age 25, as planning to say, "Well, I'm interested in sexual health, well-being; would you mind taking this, you know, with me?" Another said he would use persuasion, talking up the uniqueness of the test and "how great it is." Others said they would make the test a condition of forgoing condom use or as a sign that a relationship had moved to steady from casual status.

Most saw a common problem in using the test with casual partners in spontaneous situations. "To wait 20 minutes to see what would happen would put the brakes on whatever crescendo you're having," said a 40-year-old white man. "It's a buzz killer."

A more serious concern, one raised by the test's opponents, is how users would react to a positive test. "There's a lot of potential opposition and clinics might not be crazy about direct access in a private setting with no personnel with them if they get a positive result," said Mr. Carballo-Diéguez.

OraSure's Mr. Michels said he had heard those concerns, but felt they were not an obstacle.

"Those objections have been raised and discussed, there has been an opportunity for public comment, but there is broad support for this test."

Mr. Frasca added, "There has been a progressive loosening of restrictions on HIV testing," and that many people feel the FDA will approve the application.

In announcing its latest FDA submission, OraSure cited federal Centers for Disease Control and Prevention statistics on the need to expand testing. There are approximately 1.2 million people in the U.S. who have HIV and about 240,000 are unaware of their status, according to the company.

Meanwhile, the test subjects had different ideas on the best strategy for dealing with a positive test. Some said they would offer deep sympathy and ask how to help. A minority said they'd be out the door. "Man, got to go," said a 21-year-old black man describing his likely reaction.

The researchers are now following up with a second study in which they have distributed tests for home use and will later ask subjects to report on their experiences using them. So far they have not studied the heterosexual population, but said it could have widespread use. They could even see a scenario—remote—in which a person could test a partner surreptitiously. "It's come up; I guess you could swab someone when they were sleeping, but it would very difficult," said Mr. Carballo-Diéguez.

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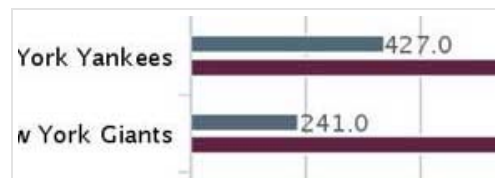
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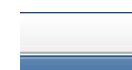
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