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Home Testing for HIV

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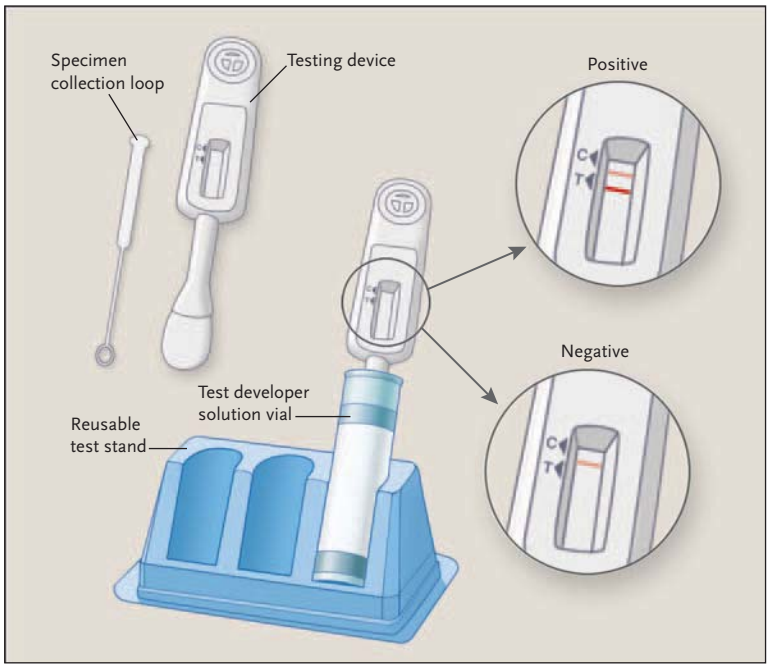
The Food and Drug Administration (FDA) has been struggling for nearly two decades over the possible approval of a do-it-yourself home test for human immunodeficiency virus (HIV). Now, after years of politicking and lawsuits, it finally looks possible. Last November, after OraSure Technologies announced that it was seeking over-the-counter status for its rapid HIV-antibody test, the FDA convened a panel of experts to determine the requirements for approval of a home test. The OraQuick test, which is widely used in clinics, works like a home pregnancy test, except that it uses oral fluid instead of urine.

The November 2005 meeting, held in Gaithersburg, Maryland, was attended by an odd group of bedfellows — physicians, evangelists, gay activists, venture capitalists, and public health officials — who assembled to lobby the Blood Products Advisory Committee about over-the-counter availability. Their arguments were as diverse as their backgrounds, but only 2 of the nearly 20 people who spoke voiced concern about bringing a home HIV test to market. The overwhelming majority argued that it is long overdue.

Tom Donahoe, a young AIDS activist and founder of Who's Positive, an HIV outreach and advocacy organization for young people, traveled from State College, Pennsylvania, to share his story at the hearings. Donahoe grew up in a rural town where, he says, gay men were surrounded by shame and stigma. As the eldest son in a military family, he was an unlikely advocate for gay rights, but he became active in the gay community during his first year at Pennsylvania State University. When he decided to get tested for HIV, he avoided the only AIDS service organization in town, where many of his friends worked, opting instead for the anonymity of a new primary care doctor. One week later, he received a telephone call from the physician and knew instantly that he had tested positive. He recalled arriving at the doctor's office, where a faceless white coat entered the room, announced that he had HIV, and sent him home. "I left without any resources," Donahoe said. "I didn't have a single pamphlet or number for a crisis hotline. It was, like, here's the news, have a good day."

Donahoe's experience is an AIDS activist's worst nightmare. When the first HIV test was developed in 1985, activists lobbied



The OraQuick Rapid HIV-Antibody Test, Showing Positive and Negative Results.

for unique legislation to protect infected people from discrimination. In an unusual move, doctors were required to obtain specific permission before testing patients for an infectious disease. Many states mandated that health care providers offer face-to-face counseling before and after every HIV test to ensure that people who tested positive received support. There were also laws dictating how positive results were to be reported, which hampered the routine contact-tracing process. Many states did not allow HIV status to be included in the medical record.

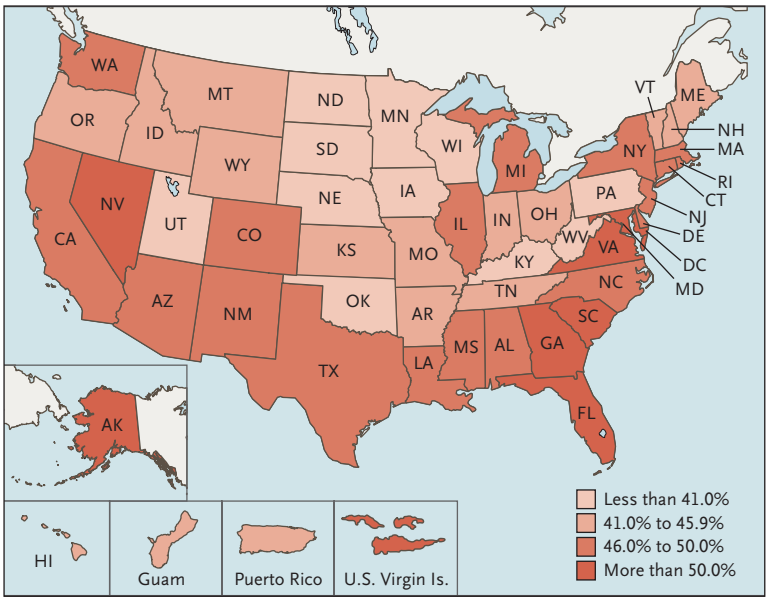
In 1986, entrepreneur Elliott Millenson approached the FDA with plans to manufacture a test for home use. The skeptical agency deliberated for two years before declaring that testing should be restricted to health care professionals. Millenson filed a lawsuit against the FDA, which then held its first public hearings about home HIV tests in April 1989. Venture capitalists were disappointed, however, when a powerful coalition — including several congressmen, the American Medical Association, the Centers for Disease Control and Prevention (CDC), and gay activists — objected to home tests, arguing that they might be inaccurate or increase the risk of suicide. AIDS activists reinforced the latter point by distributing copies of the obituary of a man who had jumped off the Golden Gate Bridge after learning that he was HIV-positive.

Those fears, however, were never realized. Over the next few years, as more HIV treatments became available, the FDA reversed its stance, and in 1996, it approved two home-collection kits for HIV, including one developed by Millenson. Both were available over the counter but required users to send their blood to a laboratory for HIV testing. Within a week, consumers could anonymously obtain their results and counseling by calling a toll-free telephone number. Although some observers bemoaned the loss of face-to-face counseling, others argued that the home tests provided increased access and much-needed anonymity and privacy.

The FDA's approval of the kits meant that anonymous HIV testing was suddenly available nationwide, even in states where it was illegal. Several states tried to block sales, citing laws that mandated reporting the names of HIV-infected persons. The FDA responded that its approval trumped state laws, and the tests were launched.

Within a year, more than 175,000 people purchased kits, and the expanded screening was not associated with any reported increase in the rate of suicide.[1] This was welcome news to public health officials, who were concerned about waning vigilance regarding HIV prevention after the advent of antiretroviral therapies. They were encouraged by studies showing that HIV-positive persons modify their behavior by engaging in fewer high-risk sexual encounters after learning their serologic status[2]; thus, expanded testing should decrease HIV transmission and permit increased access of infected persons to effective therapies.

Unfortunately, an estimated 25 percent of HIV-positive Americans do not know their serologic status, and public health officials believe that this population is fueling the 40,000 new cases of HIV infection that occur each year. Since the late 1990s, the United States has been losing ground in the fight against HIV and AIDS. The number of deaths from AIDS has plateaued rather than decreased, and the rate of new HIV infections is on the rise in some populations.



Percentage of Persons between the Ages of 18 and 64 Years Who Reported Ever Having Received an HIV Test, According to State, as of 2001.

Data are from the Centers for Disease Control and Prevention.

Most HIV-positive people in the United States receive medical care but are not tested for HIV until they become symptomatic. Given this alarming fact, the CDC recently issued new recommendations to expand testing by integrating HIV screening into routine health care services both in traditional medical settings and in the community. The guidelines also include the testing of all pregnant women unless they specifically opt out and annual retesting of persons at high risk. The CDC's aim is to minimize barriers to testing, including patients' fear of being stigmatized and physicians' reluctance to test. For the first time, the CDC no longer recommends prevention counseling at the time of testing. The guidelines are a radical departure from current medical practices (and state laws), which treat HIV infection differently from other infectious diseases and focus screening on high-risk populations.

Rapid testing plays a key role in the new CDC strategy. In 2000, more than 30 percent of Americans who were tested were lost to follow-up because they did not return for their results, which can take up to two weeks with traditional tests. Rapid testing provides immediate results, which facilitates the referral of HIV-positive patients to treatment programs. Preliminary results from a recent CDC study showed that 80 percent of Americans in whom HIV infection was detected by a rapid test in a hospital, emergency department, or clinic sought care.[3]

Four rapid tests have been approved by the FDA, but only the OraQuick test involves oral fluid instead of blood. The user swabs the inside of the lip, collecting whatever antibodies are expressed along the gum line, and places the swab inside a vial containing developing solution. Results are available in 20 to 40 minutes. Another rapid test, produced by MedMira and marketed over the counter in Hong Kong, is blood-based but yields results within three minutes.

There are still a number of issues to be addressed before the test comes to market. OraSure reports a test sensitivity of 99.3 percent and a specificity of 99.8 percent, but recently public health officials in San Francisco, Los Angeles, and New York reported high rates of false positive results at a few sites. In 2005, San Francisco public health clinics ran 9400 tests, of which 250 were positive. On confirmatory testing, approximately 49 appeared to be false positive. Officials were aware of the risk of false positive results, particularly in areas with a low incidence of HIV infection, but this was a higher rate than expected in a high-risk population. Although this apparent flaw may be an aberration, an investigation is ongoing. In the meantime, at least six test sites in these three cities have stopped using the test, although Dr. Bernard Branson, associate director of laboratory diagnostics at the CDC's National Center for HIV, STD and TB Prevention, argues that it would be premature to abandon it now.

Even if these issues are resolved, many physicians are leery that users will have difficulty understanding the nuances of the test and may misinterpret preliminary results as final. There would inevitably be false positive results that could cause substantial psychological distress. Similarly, false negative results, which may be obtained during the window between infection and seroconversion, could provide a false sense of security and potentially promote risky behavior.

If home use of the test is approved, physicians will need to help educate their patients about

window periods and false positive results. And clinics will need the ability to perform routine confirmatory testing, such as Western blot analyses, among patients with positive results. These measures, along with detailed educational materials in package inserts, must be part of the home-marketing strategy.

Another controversial issue is cost. Currently, laboratories pay $12 to $17 for each OraQuick kit. The company expects to raise the price if over-the-counter status is approved, but it is not sure by how much. Public health officials argue that the test must be affordable to reach high-risk populations. A pilot study, sampling 240 HIV-positive patients, showed that most would pay no more than $15 for a test.[4]

Despite concern about affordability and the potential for the misuse of results, there is still strong support for home HIV testing. During the recent rash of false positive results, officials emphasized that the test remains an excellent screening tool, and many experts argue that the only way to halt the spread of the AIDS epidemic in the United States is to make HIV tests as simple as home pregnancy tests. If those who spoke at the FDA panel meeting in November are heard, the 20-year wait for a do-it-yourself HIV test may soon come to an end.

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