Rapid HIV Home Test Wins FDA Approval

The Food and Drug Administration (FDA) approved a new home HIV test on July 3 that makes it possible for people to test themselves in the privacy of their homes. The availability of an HIV test that’s as easy to use as a home pregnancy test could be another step in the direction of reducing stigma associated with the disease and increasing the number of people who know their HIV status.

Dr. Anthony S. Fauci, longtime AIDS researcher and director of the National Institute of Allergy and Infectious Diseases (NIAID), called the new test a “positive step forward” and one that could help bring the 30-year-old epidemic under control.

Studies have shown that getting HIV-positive people onto antiretroviral drug therapy lowers the chance that they will transmit the virus to someone else by as much as 96%. Testing and treatment have therefore become crucial to prevention and are part of the National HIV/AIDS strategy, though questions remain as to how to guarantee access to care and treatment for those who test positive.

The OraQuick test, by OraSure Technologies, uses a mouth swab and gives results in 20 to 40 minutes. A previous test sold over the counter required the user to prick a finger and mail a drop of dried blood to a lab, thus making it days before results were known.

The new test has some drawbacks. While it is extremely accurate when administered by medical professionals, it is less so when used by consumers. Researchers found the home test to be accurate 99.98% of the time for people who do not have the virus. By comparison, they found it to be accurate 92% percent of the time in detecting people who do. So, while only about one person in 5,000 would get a false positive test, about one person in 12 could get a false negative.

One concern is the “window period” between the time someone gets the virus and begins to develop the HIV antibodies that the test detects. That can take up to three months.

Any positive test needs confirmation in a doctor’s office, the FDA said, and people engaged in high-risk sex should test themselves regularly.

The agency does not intend for the home test to replace medical testing, but instead to provide another way for people to find out their HIV status, said Dr. Karen Midthun, director of the FDA’s Center for Biologics Evaluation and Research.

Of concern to those who work as testers in AIDS service organizations is the issue of pre- and post-test counseling, especially for those who test positive. “My main concern is that anyone who got a positive result might harm themselves,” says Derek Worley, a tester and member of the Prevention Department at Test Positive Aware Network. “Finding out you’re positive can be a traumatic event, even if a trained counselor is there with you. I can’t imagine it would be any easier if you’re alone,” he added.

OraSure intends to set up a toll-free, 24-hour phone line to provide answers to questions and guidance to those who test positive about how to connect with care and service providers.

The home test should be available in 30,000 pharmacies, grocery stores, and online retailers by October, said Douglas Michels, OraSure’s chief executive. The price has not yet been set. But he said it would be higher than the $17.50 now charged to medical professionals because the company will do more complicated packaging for the home kit, open the 24-hour hotline, and advertise to high-risk groups, including gay men, blacks and Hispanics, and sexually active adults. Still, he said, it will be kept inexpensive enough to appeal to people who might want to buy several a year. In addition, because the FDA approved the home test only for people 17 and older, retail stores may ask customers to show ID.