

FDA panel: DIY HIV testing a good thing

By ACSH Staff — May 17, 2012

In a unanimous decision, an FDA panel [voted Tuesday to approve](#) ^[1] the first rapid, over-the-counter HIV test. Already in use in professional health care settings since 2004, the OraQuick HIV test uses a mouth swab and returns results in about 20 minutes. Although the home test has only a 93 percent accuracy rate, the FDA advisory committee determined that the benefits of the at-home test outweigh the risk of false negatives.

Based on a trial conducted by Orasure, maker of the test, the FDA determined that OraQuick would miss about 3,800 HIV-positive people annually, while correctly identifying about 45,000. The test could also help prevent approximately 4,000 new cases of HIV per year, which is important, considering that the rate of new infections has held steady at about 50,000 cases annually over the last 20 years.

The test is also important since about 20 percent or 240,000 people of the 1.2 million HIV carriers in the U.S. are unaware of their HIV-positive status. And a recent survey of gay and bisexual men found that 84 percent would test themselves for the virus more frequently if they had the option of purchasing an OTC HIV test. Although the test is not perfect, its potential net benefit is quite large, ACSH's Dr. Gilbert Ross points out.

Currently, other at-home HIV tests are available, but they require a blood sample, which must be sent to a laboratory for results thus making them less attractive to consumers.

The FDA panel of experts also stressed the need to include a toll-free number on the OraQuick test so that if users do test positive, they can get in touch with proper counseling and medical care immediately something Dr. Whelan believes is hugely important.

This is just another example of how the face of AIDS has changed in the past fifteen years, ACSH's Dr. Josh Bloom points out. Instead of having to wait weeks to find out if you were HIV-positive, and then having little you could do about it, people can now get the results almost immediately. And with one or two pills per day, an HIV-positive person can now stay healthy for a long time. Quite amazing, really.

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