

In a flash

The first rapid HIV test is approved in Canada

by Carole Lunny

In 2000, Health Canada approved the first rapid HIV test for use in health facilities in Canada, although it was subsequently withdrawn from the market following concerns about accuracy. That same year, Canadian testing guidelines were published.

Since then, BioLytical Laboratories, based in Richmond, BC, has developed a rapid HIV test called the INSTI HIV-1 Antibody Test. It is a rapid, in vitro qualitative test for the detection of antibodies to Human Immunodeficiency Virus Type 1 in human whole blood, serum, or plasma. The test can be administered and confirmed in 60 seconds, however, the “presumptive” result of a positive rapid test would need to be confirmed by the usual laboratory procedures. If a patient’s test yielded a negative result, no subsequent lab testing would be required.

The current procedure for testing for HIV is to first use the enzyme-linked immunosorbent assay, or ELISA test, and then confirm with an immunoblot blood test, also known as a Western Blot. The rapid test can save the healthcare system up to 30 percent by eliminating one laboratory test. The one caution is that the rapid test can cause false positive results when a person presents with multiple myelomas.

Approved for HIV-1 testing by Health Canada in October 2005, the INSTI HIV-1 Antibody Test has a 99.6 percent accuracy rate. (Health Canada and the US Food and Drug Administration’s regulations say that an HIV test cannot fall below a 98 percent accuracy rate.) Currently, INSTI HIV-1 Antibody Test is being pilot tested by the Hassle Free Clinic, a Toronto-based anonymous clinic, and by the BC Centre for Disease Control. The test is still in trials for approval of rapid testing for HIV-2.

The test is approved for sale in Europe and is going through the approval process in the US. However, even if the FDA approves the rapid HIV test in the US, BioLytical would not be able to sell it there because Viread Inc. already owns the rights to testing of the HIV-2 virus in the US.

The test is approved for sale in point-of-care settings such as hospitals, clinics, or doctor’s offices, and is designed to be administered by a healthcare professional. The test is not authorized for over-the-counter sale or use at home, although Health Canada hasn’t regulated the distribution of its sales, so it could potentially make its way to Internet pharmacies or the black market.

The cost of the testing kit is \$7.00 to \$9.00 per test, if ordered through BioLytical. However, clinics may charge more. The test has a shelf life of 12 months but will remain stable for up to 18 months.

Pre- and post-test counselling for HIV has been considered best practice for healthcare providers. The reality, however, is that some healthcare providers often don’t provide sufficient, if any, counselling when testing for HIV. With the approval of the rapid test, there is an even greater need to develop and train all healthcare providers in good communication and counselling skills. Informed consent is a central element of good HIV testing practices and of protection of human rights for those being tested. ⊕



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