Home HIV Test Kits

Adopted by the Positive Living Society of British Columbia
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Preamble

The Positive Living Society of British Columbia is mandated to empower our members by providing information about all available healthcare options and advocating for safe access to all health services. Where services do not exist, or are unavailable, the Society works on behalf of its membership to secure them and/or to ensure that each individual has real alternative choices.

Home HIV Test Kits

HIV home test kits are an important health care option currently unavailable in Canada (except where they are imported illegally through international mail-order operations or by cross-border shopping). Home tests kits allow people to use a blood sample or oral swab to test themselves for HIV type 1 (HIV-1) outside of a healthcare setting and without a healthcare provider present. These tests differ from Point of Care (POC) tests, such as the Health Canada-approved INSTI HIV Rapid Test. While both home test kits and POC tests are easy to administer and can provide rapid results, POC tests must be used in a clinic or healthcare setting, and are usually provided free-of-charge to the person being tested.

Home test kits provide information on a person’s HIV status that is essential to properly care for one’s wellbeing and health. The convenience, simplicity, and privacy of this low-barrier form of testing make them a valuable instrument that can increase the number of people who test for HIV, thereby enabling them to know their HIV status and so take necessary steps to care for their health. Consequently, Positive Living BC contends home test kits must be made available to Canadians.

While it is necessary to make home test kits available to Canadians, it is equally necessary, in fact, imperative, to regulate home test kit quality federally and accompany such tests with a supportive structure of information that outlines home test kit limitations and connects people to suitable healthcare services and assistance, both before and after testing for HIV.

The United States Food and Drug Administration has approved two home test kits for use. One is the Home Access HIV-1 Test System, a finger-prick blood test kit. The blood sample is sent to a lab and test results are obtained anonymously over the phone. When using this test, it is not necessary to confirm results by performing a second test, as the manufacturer performs confirmatory testing before making results available. The second approved test is OraQuick, an oral swab test. This test detects HIV antibodies in saliva and results are read at home by the user. Users are advised that positive results must be confirmed by a second test taken at a clinic.
Because federally approved and regulated home test kits are not available to Canadians, people can and do order such kits from international suppliers. Purchasing unregulated medical supplies can result in people using unauthorized, defective tests that deliver incorrect results. Health Canada has received reports of companies selling unlicensed and unauthorized home test kits online and has issued advisories warning against the purchase and use of such kits. [1] Providing publicly funded, federally regulated home test kits would eliminate this dangerous situation while improving and increasing access to HIV testing.

However, inaccuracy of home test kits has produced valid concerns about their widespread use, especially as regards oral test kits. Because the level of HIV antibody is generally lower in oral fluid than in blood, oral testing is not as accurate as blood sample testing, though both blood and oral home tests can give inaccurate results. Any home test kit must be clearly labeled with information on the test’s accuracy, including statistics on how often the test produces false-negative and false-positive results.

A “false-positive” result occurs when a person receives a test result showing that they are HIV-positive, when in fact they are HIV-negative. In regards to oral testing, studies show the OraQuick test is “as accurate (99.9% of the time) at identifying HIV-negative results as blood-based testing done in a lab by trained professionals,” [2] meaning that one false-positive result would be expected out of every 1,000 test results in uninfected individuals. As for the Home Access HIV-1 Test System, which uses a blood sample, studies have shown this test identifies 99.5% of HIV-1 negative samples. [3]

“False-negative” test results (when a person receives a test result showing that they are HIV-negative when in actuality they are HIV-positive) can occur using an OraQuick test if the user completes the test incorrectly by not swabbing the gum line. “False-negative” test results can also occur if a person has taken part in an HIV transmission risk event in the past three months, such as unprotected sex, since the OraQuick test relies on the detection of antibodies in the saliva, which can take up to three months to develop. OraQuick tests are “91.7% accurate at identifying HIV-positive test results. This means that almost 10% of people who test HIV negative using OraQuick are actually HIV-positive.” [4] Alternately, clinical studies have shown that the Home Access HIV-1 Test System, which uses a blood sample, “is able to correctly identify 100% of known positive blood samples.” [5]

Along with concerns about inaccurate test results, there is also the critical matter of whether or not people using home test kits will seek out and receive appropriate pre-test and post-test care. Before and after testing, healthcare professionals can link people testing for HIV with necessary healthcare options by providing information and recommendations for treatment and counselling, as well as options for reducing future risk events. However, for people using home test kits, this vital support is absent.

In regards to post-test care, there are also concerns about how people will react upon learning test results. For example, people who have performed oral tests may not complete the second confirmatory test needed to verify their results. Receiving test results, whether positive,
negative, accurate, or inaccurate, is a situation that needs to include appropriate post-test care and counselling.

To address the above concerns, home test kits available in Canada must include a supportive structure of information that outlines test limitations, their accuracy rate, and provides information to connect people to care, counselling, and support before and after testing. Supports similar to those offered with home test kits in the United States could be provided—for example, Oraquick, through its website and through information sheets in its test package, offers:

- a 24-hour toll-free number to a support centre;
- a list of warnings and precautions that inform the user about the test’s limitations;
- links to pre- and post-test counselling and care; and
- information on HIV and risk and prevention.

In addition, the Home Access Test, which markets itself as a counselling and testing service, provides a toll-free telephone support line to assist with questions about testing and test results. Pre- and post-test counselling are built into the test itself—testing begins with a phone call to register the test, during which the patient also receives pre-test counselling. After the test is completed, results are obtained via phone, during which the patient receives post-test counselling that includes medical and social referrals.

In BC, Positive Living BC suggests such kits include support and counselling information keyed to area health authority resources (including local HIV/AIDS organizations, if any) and that over-the-phone consultation (if any) be provided by the BC Centre for Disease Control (BC CDC).

Home test kits accompanied by a supportive information structure similar to that outlined above—with sufficient local information supplied—not only have the ability to increase the number of people who know their HIV status and can therefore take necessary steps to care for their health, but also have the potential to increase HIV testing among populations that are hard to reach or that have historically been unwilling to get tested. Research has shown “that HIV self-testing is acceptable among MSM [men who have sex with men] who have never tested for HIV, a key population to reach for HIV testing.” [6] Additionally, home test kits could be used by people living in locations where testing is not offered, such as remote rural towns, or in situations where concerns over anonymity, privacy, or stigma prevent people from testing.

To avoid creating a division of care, it is important that home test kits be made available free of charge to Canadians. In the United States, an Oraquick test costs approximately $40.00. Currently in Canada, all HIV testing is free, and new and additional methods should remain so in order to ensure providing equal access to this healthcare service by people of all income levels. In BC, we suggest that the BC CDC make kits available free of charge (perhaps supported by a levy on the STOP HIV/AIDS funding provided by the provincial Government to the various health authorities).
Recommendations

1. Home HIV test kits are an important tool that can help people know their HIV status and consequently, receive appropriate healthcare. As such, home test kits should be made available to Canadians.
2. Home test kits must be standardized and regulated by Health Canada.
3. Home test kits must be clearly labeled with information on test limitations, including the test’s false-positive and false negative rates.
4. Home test kits must be accompanied by information detailing where the user can receive appropriate pre- and post-test counselling and care; such information should, wherever possible, include local support and counselling contacts.
5. The federal government, assisted by the Positive Living Society of British Columbia, the BC Centre for Disease Control (BC CDC) and the Canadian Treatment Action Council, should create an information and support service for pre- and post-test HIV care, to be offered with home test kits.
6. Because current HIV testing in Canada is free, home test kits should be made available at no cost to the user, in order to avoid creating a division in HIV testing and care. In BC, this can be done through the BC CDC.