

Information on HIV self testing for health care and community providers

BULLETIN: JULY 2020¹

In the coming weeks, Health Canada will decide whether the first HIV self/home-test (INSTI HIV Self Test®) will be approved in Canada. The test is made by a Canadian company: bioLytical Laboratories (www.bioLytical.com). The exact date of availability in Ontario will depend on Health Canada's decision, and when the manufacturer retailers, such as pharmacies, and others make the test available.

HIV self tests are used in several countries. Research shows that some people prefer self-testing because it is convenient and confidential. The enhanced privacy of self testing makes it an effective way to reach first-time testers and those who otherwise would not test for HIV. For more on the research associated with HIV self testing please see RESEARCH SUMMARIES below.

The following are a series of Frequently Asked Questions (FAQ) based on available information. This document addresses questions in the following areas:

- Access to HIV self testing
- How the test works
- Timing and accuracy of the test
- Considerations for organizations supporting self testing clients
- Additional information resources on self testing
- Research Summaries

As we learn more, we will update this document.

ACCESS TO HIV SELF TESTING

What is HIV self testing?

HIV self testing means that a person can obtain/purchase their own test, do the test themselves and get their results right away without having to go to a clinic or doctor's office (like a home pregnancy test). The self test is different from other HIV tests on the market for public use, such as mail-order tests which require a person to send a sample of their blood to a lab for testing.

The self test is a screening test. Screening tests rapidly determine when a person is HIV negative and flag people who require further testing. Individuals who test positive through a screen test, require follow-up confirmatory testing to be diagnosed with HIV.

How will the test be available?

The test will be available for purchase, with an anticipated cost between \$25 and \$45 dollars. The manufacturer is planning a direct mail order website, and the test will likely also become available in Ontario pharmacies. Several research projects in Ontario will be providing free test kits to certain individuals, however these are all pilot projects. Some organizations may be contacted by these studies

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to participate in the distribution of tests and/or to provide supervised or supported self testing.² Organizations should carefully consider a range of factors associated with these roles prior to implementing new programming. (see details further below.)

Currently, there is no government program to provide free self test kits to Ontarians. However, it is vital that Ontario-funded service providers be aware of this new HIV testing option and can answer client questions about the test and help those who test positive to link to confirmatory testing and HIV treatment and care.

HOW THE TEST WORKS

How does the test work?

The self test is like the one used by the Ministry of Health's HIV rapid/point-of-care testing program which uses the INSTI HIV-1/HIV-2 Antibody Test® and is produced by the same manufacturer. It detects the body's immune response to HIV (antibodies), not the virus itself. If a person has been infected with HIV, it will take between three weeks to three months before the test can detect HIV infection. (This period, when the ability of the test to detect infection is rapidly increasing, is called the "window period".) A positive self test result at any time during the window period, will need to be confirmed with further testing, regardless of when the initial exposure occurred.

To do the test, a person will prick their finger, take a single drop of blood with the tools provided and read their results. The test produces results almost immediately. The whole process can take less than five minutes.

The test kit's package insert will likely include an information help line where people can be assisted in seeking additional information and resources.

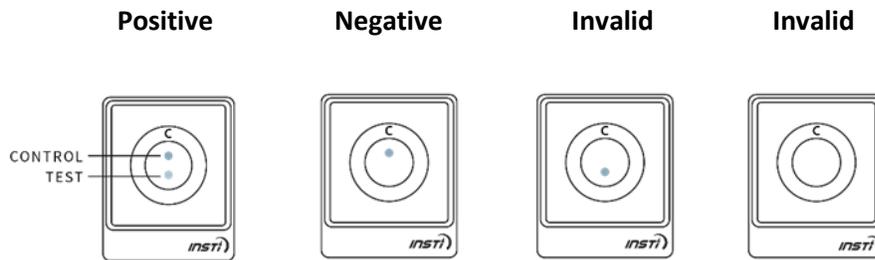
What do the results look like?

The test has a built-in control spot marked by a "C" on the device to let people know whether they've performed the test correctly. If there is no control spot, the test did not work (Invalid). The test also has a test spot, for a total of two possible spots.

If two blue spots appear, the test is positive. Confirmatory testing will need to be done by the Public Health Ontario Lab to make a final diagnosis. Confirmatory testing can be done through a sexual health clinic and/or a physician who requisitions the test. Confirmatory testing may be done anonymously at designated clinics.

If only one spot appears (control spot), and testing is taking place three months after the last known/possible exposure (i.e. outside the window period for HIV infection), then the result is negative. No further lab testing is recommended. If no control spot appears, regardless of whether a test spot appears or not, the test is Invalid and must be discounted. A new test will need to be performed.

² Supervised self testing generally refers to the presence of a health care provider (HCP) during self testing. The HCP may be asked to assist the client with the testing procedure, interpret a result, troubleshoot, provide pre and post-test counselling, and refer clients to services. See: Pant Pai N, Sharma J, Shivkumar S, Pillay S, Vadnais C, Joseph L, et al. Supervised and unsupervised self-testing for HIV in high- and low-risk populations: A systematic review. PLoS Medicine. 2013;10(4).



What happens with the results of the self test?

The HIV self test is a screening test designed to identify people who need further testing to confirm a diagnosis of HIV. The result is the private information of the person taking the test and should be maintained as confidential subject to any legal requirement to disclose it, such as a warrant. If a staff member from your organization participates in supervising a self test, there is no requirement to report the result to public health or to other staff members - providing that the staff supervising self testing are not physicians or Nurse Practitioners. Note that both physicians and NPs are required under Section 26 of the Health Protection and Promotion Act (HPPA) to report an HIV positive result (agent of a communicable disease), including HIV positive results from supervised self testing. Note as well that the subsequent laboratory that conducts the test, and confirms an HIV positive result, would also have a duty to report to public health. Clients who have a positive self test should be advised to seek confirmatory testing through a testing clinic or physician. They can also be linked to care and treatment (where they can obtain confirmatory testing).

It is important to communicate to clients who receive a positive self test result the benefits of early diagnosis, initiation of treatment and reduction in HIV viral load to undetectable levels for optimal health outcomes. They should also know that once they are undetectable, they cannot transmit the virus (U=U). It is important for clients to understand that until they are undetectable, they should protect their partners (through condom use, sterile, single use drug using equipment, and/or abstinence).

Confirmatory testing options, include:

- Nominal testing by a physician or a sexual health clinic. Positive results on the confirmatory test are reported to public health, and the client is expected to work with their physician or public health to notify any sexual or drug using partners about their HIV status.
- Anonymous testing offered by designated sites in Ontario. Positive results are reported to public health without the person's name, and public health only becomes involved at the client's request. A person diagnosed with HIV through anonymous testing has a responsibility to notify their sexual and drug using partners of their HIV status. Clients who seek treatment and care will generally be retested nominally by their physician and this result will be reported to local public health.

TIMING AND ACCURACY OF THE TEST

Is the self test accurate?

Yes. When the test is done correctly, it will detect HIV more than 99% of the time once the body's immune response has produced antibodies to the virus that can be detected by the test (i.e., after the three-week to three-month window period). However, a positive self test result must be confirmed with a follow-up blood test by the Public Health Ontario Lab.

It is extremely important for those who self test to carefully read and follow all labeled directions. Even when used according to the labeled directions there can be a small number of false negative and false positive results. The INSTI HIV-1/HIV-2 Antibody Test® (which is the technology the INSTI self test is

based on) is very sensitive and specific. Sensitivity is 99.6% (i.e., the percentage of results that will be positive when HIV is present). This means that a very small number of people could test false negative with the INSTI self test. In a Canadian study, the self test was performed by untrained users and had a specificity of 99.5% (i.e., the percentage of results that will be negative when HIV is not present). This means that up to 5 false positive results could be expected out of every 1,000 tests in uninfected individuals. This is an important reminder for people to obtain confirmatory testing of all self test positive results.

How soon after an HIV risk should a person take the test?

A person can take the test as early as three weeks after exposure. The performance of the INSTI HIV Self Test® is like that of the INSTI HIV-1/HIV-2 Antibody Test®. Research shows that the likelihood of detecting an HIV infection increases throughout the three-week to three-month window period, reaching the high level of accuracy discussed above at three months. Individuals may choose to test frequently within the window period, and they will have the highest level of confidence in a test done three-months after exposure.

If an individual reaches out to your organization immediately following a high-risk exposure, they should be advised to wait three weeks before testing. At three weeks, they can choose to test using a self test or a rapid/POC test (the POC test has been shown to identify HIV antibodies at three weeks), but they should also be advised to obtain lab-based testing to benefit from the P24 antigen test only available at the Public Health Ontario Lab. P24 antigen is a protein of the HIV virus and can only be detected between 2-4 weeks after exposure. Self tests and rapid/POC tests cannot detect P24 antigen. If a person tests negative at three weeks, they can be advised to test again at six weeks, then again at three months.

If the person was potentially exposed in the **past 72 hours**, they are a potential candidate for HIV Post-Exposure Prophylaxis (PEP). They may wish to visit their local emergency department for further assessment. Emergency care providers can prescribe this preventative treatment, which is free to anyone who has been sexually assaulted, or they could be prescribed PEP by another health care provider where payment can be covered by private health care, government funded drug programs, or out of pocket payment.

Under what circumstances should a person take the test?

Deciding on when and how to take the test will be a personal decision. Some people may choose to take the test alone. Others may want support. People should give careful consideration about whether they want someone else to see their results at the same time as they do. They should feel comfortable and safe with whomever and wherever they take the test. When talking to clients about self testing encourage them to identify the people in their life that they would turn to for support if the test were positive, even if they wish to take the test alone.

Clients should be strongly discouraged from pressing current or potential partners to take the test. HIV testing should always be the outcome of a thoughtful, proactive decision to protect one's own health.

CONSIDERATIONS FOR AGENCIES SUPPORTING SELF TESTING CLIENTS

What supports can community agencies provide people seeking self testing?

Community agencies can consider the following:

- Ensure staff are informed about the availability of self testing in Ontario and the process of HIV self testing, including where to obtain a test.

- Provide emotional and informational support for individuals considering HIV testing, including self testing, and supporting independent decision making around HIV testing. For training modules on HIV test counselling and assessing risk see <https://hivtestingontario.ca/poc/counsellor-training/>
- Encourage prompt testing whenever a person has experienced a potentially high-risk exposure to HIV – either self testing, rapid/POC testing, or Public Health lab testing.
- Talk to clients about their HIV risks and the need for testing and self care, including the possibility of HIV pre-exposure prophylaxis (PrEP) for those at-risk. Clients can be directed to <https://ontarioprep.ca>, which includes an online tool to help them determine if PrEP is right for them.
- Support clients who have had a positive HIV self test and help find confirmatory testing and follow-up HIV care within local communities. Services to help find such resources are listed below.
- Provide social and emotional support services to anyone who tests HIV positive.

Can organizations support clients in conducting self testing?

In some jurisdictions where HIV self-testing is approved, community organizations offer supervised or supported self-testing. In supervised self-testing, typically a health care provider (often a nurse) is present with the client when they take the HIV self test to help them complete the test and interpret their results, and to provide other supports, such as pre and post-test counselling. (For more information on other jurisdictions, see the links below to the OHTN’s Rapid Responses.)

It is important for agencies to be aware that in Ontario some parts of HIV testing – such as pricking someone’s finger to draw blood and interpreting test results (i.e. giving a diagnosis) – are restricted to regulated health professionals, such as physicians and Nurse Practitioners.

Self tests are specifically licensed for people to do the test on themselves. This means people who use a self test are taking on the responsibility of doing the test correctly and interpreting their own results. If staff are asked to help with testing, they may become responsible for ensuring the test is done correctly, and if asked to interpret the result, they may be put in the situation where they are determining whether someone is HIV positive.

If agencies choose to provide support to individuals seeking self testing, it is advisable that they NOT:

- Complete the test on behalf of the client, especially not to conduct the finger prick of the client’s skin.
- Read the results and indicate to the client that they have HIV; instead, they may choose to confirm the number of spots that appear on the test and remind the client that the self test is a screening test that requires confirmatory testing if positive.

The following are some programmatic considerations:

- HIV testing is provincially regulated, and HIV diagnoses can only be delivered by a regulated health professional, organizations should consult a lawyer before implementing a supervised self testing program.
- Protocols should be developed for staff, including: obtaining informed consent prior to observing self testing, reviewing test results, collecting and retaining information, confidentiality and privacy.
- Self testing may be interpreted as a clinical service requiring a change in insurance coverage, which could result in higher insurance costs. Organizations should consult their insurer.

Other, more practical considerations, include:

- Ensure adequate resources to manage a new program.
- Plan for adequate private space for testing, and biohazard waste disposal (and kit storage space if providing kits, see below).
- Train staff on how the test works and how to review results, including refresher training on test counselling and support. Training modules for the point of care testing used in Ontario clinics could be a useful reference, see <https://hivtestingontario.ca/poc/counsellor-training/>.
- Pro-actively support linkage to services: PrEP services for those who test negative and are candidates for PrEP; confirmatory testing and/or treatment and care services for those who test positive with the self test. Organizations should actively support client's linkage to services through warm referrals.
- Collect program-related data, including anonymized self test results.

NOTE: This may not be an exhaustive list of necessary considerations.

What should organizations consider if they plan to participate in programs to distribute HIV self tests to community members?

The cost may be a barrier to equitable access to HIV self tests, and some agencies may consider becoming involved in programs to distribute free or low-cost kits, either through one of the research projects being planned in Ontario, or by purchasing kits. These initiatives may also involve offering supported self testing.

In addition to the potential liability concerns related to a self testing program noted above, there are several considerations related to the handling, storage, and inventory management of supplies of self test kits:

- As a medical device, optimal kit quality and performance must be maintained. For example, kits will need to be stored according to the manufacturer's specifications. To manage potential liability, any storage space may need a temperature monitoring device and be monitored regularly.
- Kit expiry dates will need to be tracked to ensure no expired tests are distributed.

As with supervised testing, a lawyer and insurer should be consulted about this use of agency space and the associated costs and liabilities.

ADDITIONAL INFORMATION RESOURCES ON SELF TESTING

Where can a person get guidance on performing the self test?

It is anticipated that several supports will be available to individuals to help with doing a self test:

- the test kit will likely contain instructions on how to complete the test and a referral number for additional support
- the manufacturer's current video on how to complete the test is available at: https://www.youtube.com/watch?v=wiEUv_bIXQc or <https://insti.com/how-to-use>

Others are developing client support materials (The MAP Centre for Urban Health Solutions at St. Michael's Hospital in Toronto, The Ontario HIV Treatment Network, CATIE). We will continue to update this list as additional resources become available and link resources to the HIV Testing Ontario website developed by the OHTN and AIDS and Hepatitis C Programs at the Ministry of Health (<https://hivtestingontario.ca>).

Where can individuals find resources on HIV testing and follow-up services if they test positive?

The HIV self test, once available, will become part of an array of testing options and supports available in Ontario. The following resources can provide information, support, confirmatory testing options, follow-up care, social support, counselling, and legal services for individuals who have a positive test result:

- **Sexual Health Infoline Ontario** can help people find follow-up testing near them to confirm your result. The Infoline has a list of agencies that can provide anonymous HIV testing. Call them at **1-800-668-2437** (416-392-2437 Toronto). There are also chat features available at <https://sexualhealthontario.ca>.
- **Family doctor** can do follow-up HIV testing and provide HIV treatment and care.
- **CATIE** is a national resource centre for information about HIV and hepatitis C. Visit <https://www.catie.ca>.
- **Community-based HIV/AIDS services:** These local agencies support people living with HIV. They can provide emotional support, practical support, including help to find a doctor, and programs to help pay for treatments. To find a local agency call 211, a free helpline to direct people to community services.
- **HIV/AIDS Legal Clinic Ontario (HALCO):** If people with HIV have questions or concerns about their rights (e.g. confidentiality and privacy) they can contact HALCO at 1-888-705-8889 (416-340-7790 Toronto.)
- **HIV411:** This online tool provides information on local HIV and Hepatitis C programs across Canada. <https://hiv411.ca/>

HIV Testing Ontario is a new resource on testing practices and policy in Ontario for providers. Resources will expand over the coming months. Visit <https://hivtestingontario.ca> to learn more.

RESEARCH SUMMARIES

The OHTN has produced several Rapid Responses on HIV self testing:

- [HIV self-testing in high-income settings: Acceptability, potential benefits and harms, issues related to linkage to care, interventions to increase HIV self-testing](#)
- [The risk of coercion in the context of HIV self-testing](#)
- [The acceptability and use of HIV self-testing among men who have sex with men in high-income countries](#)