

CATIE STATEMENT

on the HIV self-test as a highly effective tool for increasing uptake of testing in Canada

HIV self-testing is a testing option that was licensed for use in Canada in November 2020. HIV self-testing can supplement other testing approaches, to help to reach the undiagnosed. To maximize the impact of this testing approach, we must effectively increase awareness, uptake and proper use of the HIV self-test.

The following CATIE statement begins with a simple key message, followed by recommendations for service providers and a list of available tools and resources. It also provides a review of the evidence that service providers can use to better understand the role that self-testing can play in increasing access to testing.

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Canada's source for
HIV and hepatitis C
information

KEY MESSAGE

HIV self-testing can play an important role, alongside other testing approaches, in helping to reach more people in Canada who are living with HIV and undiagnosed. Self-testing may be a preferable or more accessible option for some people since it can help to overcome some of the barriers people face when accessing testing. These barriers can include stigma, privacy concerns, inconvenience and a lack of testing options in a person's community.

For more information, please see the evidence review at the end of this statement.

RECOMMENDATIONS FOR SERVICE PROVIDERS

HIV self-testing has an important role to play in increasing access to testing in Canada. As someone working in sexual health and harm reduction, you can work to educate clients about self-testing and can support those who want to get an HIV self-test.

Below are recommendations on how you might better integrate self-testing into your messaging and work.

1. Educate clients about how HIV is transmitted and ways to prevent transmission. Help clients to understand their risk of getting HIV, to help determine how often they should test.

Some clients already have a high level of knowledge about HIV transmission and their prevention options, while others could benefit from education. Education should include topics such as what HIV is, how it is transmitted and available HIV prevention options.

Some clients may want guidance about whether they should get an HIV test and how often they should test. To help clients determine how often they should be tested, discuss the factors associated with a person's chance of getting HIV. In all discussions about testing, emphasize that testing is completely voluntary, and nobody should be pressured to get a test if they do not want to.

2. Raise awareness among clients about the testing options available in your community, including where people can access self-tests.

Be aware of the testing options available in your community and where people can access different types of tests. Standard HIV testing with a blood draw is the most common way to access an HIV test in Canada; it is typically accessed through a healthcare provider. In some regions, people can also access a rapid point-of-care test from a healthcare provider or community worker. A less commonly available option is dried blood spot testing, where drops of blood are collected on a

piece of paper. This type of testing is available in some rural regions in Canada.

Most people get tested through standard HIV testing, but some people may prefer self-testing. Self-testing is a new HIV testing option in Canada. With a self-test, an individual collects their own sample, conducts the test and interprets the result themselves. The self-test that is available in Canada uses a blood sample from a finger prick.

Many people are not aware that self-testing is available in Canada; you can work to raise awareness that this is one of the testing options available in the community. Be prepared to talk about what the HIV self-test is, how to use the kit and where people can access it.

If a client wishes to self-test, you can let them know their options for accessing it in your community.

Some ways that clients may be able to access tests include:

- Picking up free tests at a community organization.
- Ordering free tests online through a government program or research project.
- Purchasing tests online from the manufacturer (bioLytical Laboratories).

If you work at an organization that distributes kits, consider how people can access the self-tests. Studies show that novel models of delivering self-tests, such as providing them at community venues or making them available in a vending machine, can increase uptake. Secondary distribution (where a person is encouraged to distribute some tests to partners, friends or family) has shown promise for reaching people who are not engaged in healthcare.

If your organization does not currently distribute kits, but you would like to do so, you may be able to order free kits from a government program or research project to distribute to your clients.

3. Discuss the potential benefits and drawbacks of HIV self-testing compared with other types of testing. Help clients to determine the best option for them.

When you help a client to decide what HIV testing option is best for them, discuss some of these considerations about HIV self-testing:

- **HIV self-testing can be completely private.** Of all of the types of HIV tests, self-testing offers the highest degree of privacy. A person can take the test without anyone else knowing. This can be appealing to people who experience barriers to testing such as hesitancy going to a healthcare provider because of fear of stigma. This may also be

appealing to people who live in small communities where maintaining privacy in healthcare and community settings is a challenge.

- **It can be convenient.** Self-testing can be convenient especially for people who test frequently and for those who do not have easy and convenient access to HIV testing in their community.
- **HIV self-tests may be difficult for some people to access.** Free access to HIV self-tests is limited and cost can be a barrier to those without free access. Some programs may require people to have internet access and/or a smartphone to get a self-test, which can also be a barrier.
- **The window period for an HIV self-test is longer than for standard HIV testing.** The window period for the HIV self-test is between three and 12 weeks, whereas it is between two and 6.5 weeks for a standard test. If a person has had a recent potential exposure to HIV, a standard test may be a better option as it can detect an HIV infection much sooner than the HIV self-test. If someone with a recent HIV exposure chooses to use a self-test they should be counselled to test again at the end of the 12-week window period to confirm that they are HIV negative.
- **HIV self-tests provide screening results immediately.** For some people, receiving the screening results immediately is appealing. It eliminates the waiting period of one to two weeks for the standard test, which some people find stressful. However, some people may prefer to have this delay, as the waiting period gives them time to prepare for the result.
- **Confirmatory testing is necessary if a person gets a reactive (positive) result on an HIV self-test.** This requires the person to access confirmatory testing in the community and have a blood draw to confirm the result through standard HIV testing. The results take about one to two weeks.
- **Counselling may be limited with an HIV self-test.** A person can get a self-test without receiving any counselling. The lack of mandatory counselling may be a benefit to some people who prefer not to receive in-person counselling with their HIV test, for example, people who test frequently who have received this counselling on many occasions. In addition, some people do not feel comfortable disclosing personal information about sex and drug use during counselling because of fear of stigma and would prefer not to discuss this. However, for those who would benefit from counselling, some programs that

distribute self-testing kits offer counselling that people can choose to access if they wish to (for example text or phone-based counselling). Dissemination of print or web-based information is another option to provide information alongside the HIV self-test kit.

- **The HIV self-test only tests for HIV.** When people test for HIV they often get tested for other sexually transmitted and blood-borne infections at the same time because they share similar risk factors for transmission. People who want to get other tests should seek comprehensive testing through a healthcare provider rather than take an HIV self-test.

4. Encourage those who self-test to read the instructions thoroughly. Be prepared to answer questions about how the test works, and to provide tips for taking the test.

The instructions clearly describe the process for taking the test, and they also include a QR code for a video that people can watch if they prefer. However, for those who need additional support, you can help the tester to understand the instructions, which include how to do the test and how to interpret the results. Testers who have a language barrier that prevents them from understanding the instructions may require support.

For some people, it can be a challenge to draw a full drop of blood, and an insufficient sample can lead to an invalid result. Ensure that clients know that they should let a full drop of blood fall into the bottle, and they should not scrape their finger against the bottle. The liquid should be dark red after the drop of blood is added and the bottle is shaken. If it is not, the tester can add an additional drop of blood.

5. Discuss with clients who choose to self-test their plan for taking the test. Encourage clients to have a plan for what they will do in the event of a reactive result.

Self-testing allows people the flexibility to choose where and when they want to take the test. Clients may want support to think about the circumstances in which they will use a self-test. Many people choose to take the self-test at home, but self-tests can be used in any location. Some organizations may choose to allow people to take a self-test within their facilities (e.g., by making a private room available for self-testing). However, you should not do the test on a client or interpret the results for them. This is because self-tests are only licensed for a person to perform on themselves.

Encourage clients to think about whether they would like to have someone else present when they take the test. If they

want to have someone else present, it should be someone who they trust. Emphasize that getting an HIV test should be completely voluntary, and nobody should be pressured to take a test if they do not want to or are not ready.

Clients should have a plan in place in case the test returns a reactive result. Encourage clients to think about who they will talk to for emotional support if they receive a reactive result on a self-test. Make sure that self-testers are aware that they will need to get a confirmatory test in the event of a reactive result on the self-test. This is done through a standard test, which includes a blood draw. You may want to suggest a particular location or healthcare provider that your client could go to for confirmatory testing. Try to refer them somewhere where they will receive culturally appropriate and non-judgmental care.

6. Be prepared to support people after their HIV self-test, regardless of the result.

If a client shares that they received a reactive result on their HIV self-test, you should encourage and support them to access confirmatory testing. If the confirmatory test returns a positive result, you can help to connect them to care and additional support services according to their need. Emphasize that with proper treatment and care, most people living with HIV can live long and healthy lives.

If a client shares that they tested negative, ensure that they are aware of the window period and possible need for retesting. You should also discuss prevention strategies that they can use to stay HIV negative.

7. Address underlying factors that affect health and well-being.

It is important to recognize that social, economic and structural factors (such as colonization, racism, homelessness and poverty) create health inequities by affecting people's ability to access and engage with health and social services, including HIV testing services. You can help to reduce these barriers by helping clients to address other health and social issues they may be experiencing, such as homelessness or mental health challenges. Talking to clients about HIV testing offers an opportunity to engage individuals in additional health and social services. Providing referrals and linkage to other appropriate and relevant support services can help to improve a person's health and well-being.

OPTIONS FOR FREE SELF-TEST KITS (ONGOING AT THE TIME OF PUBLICATION)

- HIV Self-Testing Distribution Project (Canada-wide)
- Saskatchewan Provincial Program
- I'm Ready (Canada-wide)
- GetaKit (Ontario and Quebec)
- Test@Home (Canada-wide, for 2S/LGBTQ+ individuals)

Service provider resources

- HIV self-testing – *fact sheet*
- HIV testing technologies – *fact sheet*
- HIV transmission – *fact sheet*

Client resources

- where.to.catie.ca – *online directory showing where people can access self-tests*
- HIV Self-Testing – *webpage*
- HIV Basics – *brochure*
- I Know My HIV Status – *brochure*
- HIV Testing: What You Need to Know – *video*
- HIV Testing: Everything You Need to Know – *booklet*
- Seven Ways to Prevent HIV – *booklet*
- INSTI HIV Self Test Training Video – *video by bioLytical Laboratories*

EVIDENCE

While HIV self-testing is a new option in Canada, it has been available in other countries for many years. We can learn from the experiences of other countries about the role that self-testing can play in helping to reach people who might not have otherwise tested. Note that in some of these studies, an oral self-test that uses a saliva sample was used. Oral self-testing is not currently available in Canada.

Accuracy of the self-test

The INSTI HIV Self Test, which is the only HIV self-test available for use in Canada, is very accurate.¹ The accuracy of an HIV test is measured by its sensitivity and specificity. Sensitivity is the chance that a reactive test result will correctly indicate that a person has HIV. In other words, if the person has HIV, the test will detect it. Higher sensitivity means there is a lower chance of a false-negative result (i.e., a negative test result for

a person who is actually HIV positive). Specificity is the chance that a negative test result will correctly indicate that a person does not have HIV. In other words, if the person does not have HIV, the test result will be negative. Higher specificity means there is a lower chance of a false-positive result (i.e., a positive result for a person who is actually HIV negative).

The INSTI HIV Self Test has a sensitivity of 99.6%. In other words, if 1,000 HIV-positive people were tested for HIV, four of them might incorrectly get a negative result. Since the vast majority of people who get tested for HIV are actually HIV negative, the chance of a negative result being false is extremely low.

The specificity of this test is slightly lower, at 99.3%. In other words, if 1,000 HIV-negative people were tested, seven of them might incorrectly get a positive result. Therefore, the chance of false positives is extremely low, but it is slightly higher than the chance of false negatives. This is why all people with reactive test results are sent for a confirmatory test, which has a specificity of 100%. This means that the chance of a false-positive result after confirmatory testing is essentially zero.

Acceptability of self-tests

A review article looked at the acceptability of self-tests in the United States among populations disproportionately affected by HIV.² The 23 studies in the review included gay, bisexual and other men who have sex with men (gbMSM) and some included other populations as well. The review found evidence that self-testing is an acceptable option for gbMSM. This review, along with some more recent studies, also shows that self-testing is acceptable to female sex workers, people who use drugs, transgender women³ and African, Caribbean and black (ACB) communities.^{4,5}

Ability to reach priority populations, first-time testers and under-testers

To find and diagnose people who are HIV positive, it is important that self-testing reaches populations with a relatively high prevalence of HIV, such as gbMSM, ACB individuals, Indigenous people and people who inject drugs.

Preliminary data from two Canadian research studies on pilot projects that distribute self-test kits have found that a high proportion of people who ordered test kits were part of at least one priority population. In a pan-Canadian study called I'm Ready, 1,311 people filled out the pre-test survey required to order a test.⁶ Forty-eight percent of respondents were gbMSM, 10% were ACB, 5% were Indigenous and 3% were people who inject drugs. Similarly, a pilot project in Ottawa

called GetaKit found that of about 420 people who ordered a self-test, 54% were gbMSM, 10% were ACB, 4% to 5% were Indigenous and 2% were transgender.⁷

Self-tests may be particularly effective at reaching people who have never tested before or who do not test as often as guidelines recommend. Studies among gbMSM show that those who have never tested or who do not test as often as recommended report they are more likely to access a self-test than those who test as often as guidelines recommend. A survey in France among 5,908 gbMSM found that compared with men who had tested within the past year, men who had never tested before were 2.15 times more likely to be interested in self-testing.⁸ Also, those who had been tested before but not in the past year were 1.54 times more likely to be interested than those who had tested in the past year. An Australian survey asked 241 gbMSM about how likely they were to access a self-test.⁹ Similar to the French study, the researchers found that compared with those who tested as often as guidelines recommend, people who hadn't tested before were 2.01 times more likely to say that they were likely to take a self-test, and people who tested less often than guidelines recommend were 2.15 times more likely to do so.

Studies that looked at actual uptake of HIV self-testing show that self-testing reaches people who have never tested before.^{10,11} Most studies looking at self-testing in high-income countries have been among gbMSM. A meta-analysis of studies looking at self-testing among gbMSM estimates that 9.9% of those who take a self-test are first-time testers.¹² The two Canadian pilot studies showed that self-tests were effective at reaching first-time testers. Of the people who filled out the pre-test survey for I'm Ready, 25% said this was their first time getting tested for HIV.⁶ Of those who got tests through GetaKit, 24% were first-time testers.⁷

Evidence that self-tests find positive cases

The number of positive diagnoses made (also known as the positivity rate) for people who take self-tests can tell us if the tests are reaching the right people. Positivity rates vary considerably between studies.^{10,13} In studies done in high-income countries, positivity rates have ranged from 0.3% to 6.14%. This wide range is probably due to differences in the populations studied, the design of the self-testing program and the design of the study.

Most studies on positivity rates are observational and do not directly compare the number of positive cases identified among those who self-test with the number among those who are not offered a self-test. A randomized controlled trial among 2,665 gbMSM in the United States made this

comparison by randomizing gbMSM to receive self-test kits or not.¹⁴ In that study, over a 12-month period, 1.9% of those who were mailed self-tests reported they tested positive for HIV, compared with just 0.8% of those who were not provided self-tests. This was because those who were not provided with self-tests were less likely to get tested at all. In the 12-month period of the study, 95.6% of those who were sent a self-test took at least one test, whereas only 63.4% of those who did not receive self-tests sought out testing in that period. This study suggests that providing people with free and easily accessible self-tests is a way to reach more people who are undiagnosed.

Considerations about access and models of delivery

The way that tests are made available or distributed can affect the uptake of self-testing. The cost of the test can be a barrier for many. Several studies show that many people are open to HIV self-testing if it is free, but not if they need to pay out of pocket.² For example, a survey of 1,535 people in Philadelphia found that 90% of participants were willing to take a self-test but only 23% were willing and able to pay the market rate for the test.⁴ This discrepancy between willingness to use a test and willingness and ability to pay for it suggests that providing free tests would significantly increase uptake.^{2,11} One way to address cost-related barriers would be to use public funding to provide free self-tests or subsidize the cost of self-tests. A review found that distribution of test kits by the public health system removes cost barriers and helps to reach lower socioeconomic groups.¹¹

Besides the cost, the way that people access self-tests can affect the level of uptake. Secondary distribution may be particularly effective at reaching people who are not engaged in the healthcare system. In a survey of 828 gbMSM in the United States, 78% of participants indicated a willingness to distribute free test kits to others.¹⁵ Of those who indicated a willingness, 73% indicated they would give a test kit to their main sex partner, 72% said they would give one to a friend and 63% said they would give one to a casual sex partner. A study among Black and Latino gbMSM in California evaluated a peer-based distribution program where peers were trained to educate people about self-testing and were each given five tests to distribute.¹⁶ That study found that compared with a program targeting gbMSM, a higher percentage of first-time testers (3.51% vs. 0.41%) were reached and a higher percentage of the results were positive (6.14% vs. 1.49%).

There is also evidence that mailing out test kits is effective at increasing the uptake of self-testing.^{14,17} Other novel distribution approaches, such as providing self-tests at

bathhouses¹⁸ or in vending machines,¹⁹ have also been shown to be effective at reaching people for self-testing.

Counselling and linkage to care

In-person testing by a healthcare provider or community worker involves pre- and post-test counselling. With self-testing, there is a concern that some people might not receive the information and support that they would have received through pre- and post-test counselling. However, there are a number of ways that information and counselling can be provided to people who self-test, including in writing (either a print resource or website) or by text, phone or video call support. More research is needed to determine the optimal way to support people who self-test.¹¹

Research shows that the lack of pre-test counselling may be perceived as an advantage by some people.²⁰ In particular, people who test regularly and have a high level of knowledge about HIV may feel that receiving similar counselling and information each time they test is time consuming and not useful.²¹

Similar to pre-test counselling, with follow-up and linkage to care, more research is needed to determine the optimal strategy for ensuring those that get a reactive result receive confirmatory testing and care if the confirmatory test is positive.^{10,11} The package insert in a self-test kit often provides information on next steps after a reactive result, which may include a hotline number to call. Service providers can also make themselves available for counselling either virtually or in person.¹¹

Potential advantages of self-testing compared with getting tested in healthcare and community settings

The literature identifies many advantages of HIV self-testing. These include ease of use, convenience, the ability to maintain privacy, the ability to circumvent the stigma that may prevent people from accessing conventional testing approaches and the ability to integrate self-testing into programs.¹¹

A review paper compiled information from 18 studies that included qualitative information from people who self-test and from service providers involved in self-testing.²⁰ That review found that convenience was a consistent theme across many of the studies. People who self-test report that it gives them the freedom to choose where and when they will take the test, and it allows them to avoid having to make an appointment, travel to a clinic and wait in line. Not having to travel to a clinic was particularly beneficial for people who lived in rural areas without easy access to a testing clinic. Another theme was that self-testing offers confidentiality. In some of the studies,

participants noted that they had felt judged in the past when attempting to access HIV testing at a facility. Self-testing can help to remove this barrier, because it does not require interacting with a healthcare provider. Also, people reported that self-testing helped to normalize testing and reduce the stigma associated with getting an HIV test.

Two more recent studies echo similar themes. In a study of gbMSM who self-tested in Europe, the convenience of self-testing was a benefit often noted by people who tested routinely, who appreciated the time saved.²² Privacy was noted as a benefit among people who had not tested before and by people who were getting tested as the result of a particular risk exposure rather than seeking routine testing. In a focus group study of gbMSM in the United States, participants found self-testing appealing because of privacy, convenience and not needing to receive counselling each time.²¹ Participants also felt that self-testing would help them to get linked to care in a timely manner if they had HIV, as it would help to increase their frequency of testing and therefore get them diagnosed sooner.

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