HIV testing technologies

FACT SHEET

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HIV testing technologies are used to determine if a person has HIV. Several types of HIV testing technologies are used in Canada. These tests differ in several ways, including where the test is conducted, how the test detects HIV infection, the length of its window period, and how long it takes to receive results.

A person can be tested for HIV in a variety of different settings in Canada, including hospitals, health clinics and the community.

How are testing technologies used to diagnose HIV infection?

To test for HIV, a sample of a person's blood is taken (either a vial of blood from a vein or a couple of drops of blood from a finger prick). This blood is either tested immediately for HIV at the location where it was taken – also known as rapid or point-of-care (POC) testing – or it is sent to a laboratory to be tested for HIV (standard testing).

Laboratory testing

Most HIV testing of blood samples is conducted in a laboratory. A vial of blood is taken from the person being tested and sent to a laboratory for analysis.

The first test used in a laboratory to analyze a blood sample is referred to as a screening test. All laboratories in Canada use fourth-generation HIV testing technologies to screen blood samples.

If a fourth-generation screening test indicates that the person who gave the blood sample does not have HIV (also known as a non-reactive test or testing negative or HIV negative), no further testing is normally performed. The negative result is sent back to the healthcare provider or clinic that ordered the test so that the person who tested can be given the result.

If the screening test indicates that the person may have HIV (also known as a reactive test), then another test is performed to confirm that the result of the screening test was correct. If the *confirmatory* test indicates that the person is

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HIV positive, the positive result is sent back to the healthcare provider or clinic that ordered the test so that the person who tested can be given the result.

It can take up to one or two weeks for a person to receive their test result when laboratory testing is conducted.

Dried blood spot testing

Dried blood spot (DBS) testing uses a sample of blood from a finger prick that is collected as a blot on a card. The blood spot is dried at room temperature and mailed to a public health laboratory for screening and confirmatory testing (as described above). Currently, this collection technique is in limited use in Canada because very few public health laboratories can process the DBS cards.

DBS testing has the advantage of being able to be used in rural and remote areas because the samples are very stable once collected and do not need to be refrigerated. Dried blood spots can also be used to test for other blood-borne infections, including hepatitis B and hepatitis C.

Rapid testing

Some HIV testing in Canada occurs at the location where the blood was taken. This is known as rapid or point-of-care (POC) testing. Rapid tests are a type of screening test that can provide results within minutes. These tests only require a few drops of blood from a finger prick to test for HIV.

If a rapid test indicates no HIV infection is present (a non-reactive test result), then no further testing is normally performed and the person who was tested can be immediately informed of their HIV-negative result. However, if a rapid test indicates that a person has HIV (a reactive test result), this is *not* a final diagnosis. Instead, a vial of blood must be taken and sent to a public health laboratory for confirmatory testing. It can take up to one or two weeks to receive the results from confirmatory testing.

In some cases, if the rapid test is non-reactive and there is reason to believe the person being tested may have recently been exposed to HIV (and is in the window period – see below for more details), a vial of blood can be taken and sent to a laboratory for testing.

Self-testing

HIV self-tests allow people to test themselves for HIV in their home or other locations. In the United States, a rapid HIV test can be bought over-the-counter at stores or online and used at home (or other locations) by the person who purchased the test. No self-tests have been approved for sale in Canada; however, a self-test is likely to become available at some point in 2020. There are reports of some people in Canada purchasing self-test kits online or buying test kits in other countries and bringing them to Canada. Some HIV test kits bought online may be of poor quality and may provide incorrect results.

How do different testing technologies detect HIV infection and how long are their window periods?

Testing technologies detect HIV infection in different ways. Some tests (such as rapid HIV tests) detect HIV antibodies, which are proteins produced by the body's immune system in response to HIV infection. Other tests are able to detect specific parts of the virus itself.

No test can detect HIV immediately after infection. The window period is the time between when a person is exposed to HIV and when an HIV test can tell for certain whether they have HIV. During the window period, a test cannot reliably detect HIV and may give a non-reactive result even though the person does have HIV. The window period varies for each type of test and for each individual. In general, tests that only detect HIV antibodies have a longer window period than tests that also detect the virus itself.

Screening tests used in Canada (rapid tests and fourth-generation tests) can detect HIV within one month of infection in most people; however, the window period can be as long as three months in some individuals.

Below is a description of different types of HIV testing technologies used in Canada and their window periods.

Screening tests

Fourth-generation tests

All laboratories in Canada use fourth-generation HIV tests as screening tests. Also referred to as antigen-antibody combination tests, these tests can detect both the p24 antigen (a part of the virus) and HIV antibodies.

Tests that detect the p24 antigen as well as antibodies generally have a shorter window period than tests that detect only antibodies. This is because most people have detectable levels of p24 antigen shortly after infection, generally earlier than antibodies can be detected. However, levels of p24 antigen in the blood begin to decrease three to four weeks after infection, until they are no longer detectable, while antibody levels increase, and generally remain detectable once they appear.

Fourth-generation HIV tests conducted in a laboratory on blood from a vein can detect HIV infection in 50% of people by 18 days after exposure to HIV and in 99% of people by 44 days after exposure.

Rapid tests

Currently, only one rapid HIV screening test has been approved in Canada (the INSTI HIV-1/HIV-2 Rapid Antibody Test). This test uses blood from a finger prick and only detects HIV antibodies. Rapid tests that detect the p24 antigen (i.e., tests that detect the virus itself) are not available in Canada.

Since rapid tests detect antibodies only, they have a longer window period than fourth generation screening tests that can also detect the p24 antigen. A study using blood from a vein showed that the INSTI test can detect HIV infection in 50% of people by 26 days after exposure to HIV and in 99% of people by 50 days. However, since the study did not use finger-prick blood samples, the true window period may be a couple of days longer.

Table 1. *Summary of screening tests available in Canada*

Name of test	Availability in Canada	What the test is looking for	Median window period
Rapid test (INSTI)	Yes (some provinces)	HIV antibodies	26 days (can be up to 50 days)
Fourth-generation test	Yes (all provinces)	HIV antibodies and HIV P24 antigen	18 days (can be up to 44 days)

Confirmatory tests

The Geenius HIV 1/2 Confirmatory Assay detects antibodies to HIV. It replaced the Western blot as the standard test used to confirm a reactive HIV screening test in Canada. The Geenius assay is used by all public health laboratories in Canada that conduct HIV confirmatory tests. The Geenius assay is able to detect both HIV-1 (the most common type of HIV) and HIV-2.

The Geenius assay can detect HIV infection in 50% of people by 33 days after exposure to HIV and in 99% of people by 58 days after exposure.

Other types of confirmatory testing may be used in certain circumstances, such as when a test result is indeterminate. These include nucleic acid amplification tests (NAATs), which have the shortest window period (as early as 7 to 14 days after infection) and p24 antigen-only tests.

How accurate are HIV tests?

HIV tests are very accurate. Once confirmatory testing has been performed, the chance of a positive result being false is essentially zero. When the person being tested is outside of the window period, the chance of a negative result being false is very low. However, the chance of false positives is of greater concern for rapid tests, particularly when testing lower risk individuals.

Sensitivity and specificity

Sensitivity and specificity are measures of the accuracy of an HIV test. *Sensitivity* is the probability that a test will correctly indicate that an HIV-positive person has HIV. Lower sensitivity increases the chance of false negatives (testing negative when actually HIV positive). *Specificity* is the probability that a test will correctly indicate that an HIV-negative person does not have HIV. Lower specificity increases the chance of false positives (testing positive when actually HIV negative).

Fourth-generation HIV tests and the INSTI rapid test have a *sensitivity* of about 99.9%. In other words, if 1000 HIV-positive people were tested for HIV, 999 would test positive and one would incorrectly test negative. 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 these tests is slightly lower, about 99.5%. In other words, if 1000 HIV-negative people were tested, 995 would test negative and five would incorrectly test positive. Therefore, the chance of false positives is extremely low, but slightly higher than the chance of false negatives. This is why all positive test results are sent for confirmatory testing with the Geenius™ assay, which has a specificity of 100%. This means that the chance of a false-positive result after confirmatory testing is essentially zero.

False positives are of particular concern with rapid testing. This is because an HIV-negative person could be given a false-positive test result and then must wait for confirmatory testing to be completed, causing significant anxiety and stress. Theoretically, the risk of false positives is expected to be higher when a test is used in populations with a low HIV prevalence. However, experience from using the rapid INSTI test in Canada suggests that false positives are rare. For example, over an 18-month period in British Columbia, 17,029 rapid tests were performed, of which 1% (168) were positive, and only 5.4% (nine) of these positive results were false positives.

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