

HIV testing technologies

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 how the test detects HIV infection, the length of its window period and how long it takes to receive results.

People can be tested for HIV in a variety of different settings in Canada, including hospitals, health clinics and the community. They also now have the option to test themselves in their own home.

How are testing technologies used to diagnose HIV infection?

To test for HIV, a sample of a person's blood is taken. With the most common test, a vial of blood taken from a vein is sent to a laboratory to be tested for HIV (standard testing). There are also rapid tests available, which use a drop of blood from a finger prick to test for HIV immediately after the sample is taken.

Laboratory testing

Most HIV testing of blood samples is conducted in a laboratory. Typically, a blood sample is drawn from a person's vein and sent to a public health laboratory for analysis. A much less common method of collecting blood samples is through dried blood spot (DBS). This approach uses samples of blood from a finger prick that are collected as blots on a card. The blood spots are dried at room temperature and mailed to a public health laboratory. Currently, this collection technique is in limited use in Canada because very few public health laboratories can process the DBS cards to prepare the blood for analysis. DBS samples are very stable once collected and do not need to be refrigerated, which makes this sampling approach particularly useful in rural and remote areas.

Regardless of how the blood was collected, the first test used in a laboratory to analyze a blood sample is referred to as a screening test. All laboratories in Canada use a fourth-generation test to screen blood samples.

If the screening test indicates that the person who gave the blood sample does not have HIV (also known as a non-reactive test result or testing negative or HIV negative), no further testing is normally performed. The negative result is

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**Updated
2022**

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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 result), then another test is performed on the same sample to confirm that the result of the screening test was correct. If the *confirmatory* test indicates that the person is 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.

Rapid testing

There are two types of rapid HIV tests in Canada, the point-of-care (POC) test and the self-test. Rapid tests are third-generation screening tests. Currently in Canada the POC test and the self-test use the same technology.

Point-of-care testing

Point-of-care tests can provide results within minutes, so the client can be given the result of the test during the same visit. There is only one POC test approved for use in Canada, the INSTI HIV-1/HIV-2 Antibody Test. This test requires a drop of blood from a finger prick to test for HIV.

If the POC test indicates no HIV infection is present (a non-reactive test result), then no further testing is normally performed and the person who tested can be immediately informed of their HIV-negative result. However, if the POC 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 POC test result 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 and can provide results within minutes. The first HIV self-test was licensed for use and sale in Canada in November 2020. The INSTI HIV Self Test uses the same technology as the POC test and requires a single drop of blood to test for HIV. As with the POC test, if the self-test result is non-reactive then no further testing is required, as long as the person doing the test is out of the window period. A reactive test result requires a confirmatory test and will require the person who uses the self-test to seek out confirmatory testing.

Confirmatory tests

The Geenius HIV 1/2 Confirmatory Assay is now used by public health laboratories in Canada and has replaced the Western blot as the standard test used to confirm a reactive HIV screening test.

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) and p24 antigen-only tests.

What is the window period and how does it differ between tests?

No test can detect HIV immediately after infection. The time between when a person is exposed to HIV and when an HIV test can tell they have HIV is called the window period. The window period can vary between two weeks and three months. The length of the window period varies from person to person and also depends on the type of test used. Some people develop markers of HIV infection that are detected by HIV tests slowly and some people develop them more rapidly. Once these markers of HIV infection are present in amounts that the test can detect, the window period is over.

If someone has had a recent exposure to HIV and gets tested for HIV during the window period,

the test result may come back as negative (non-reactive) even though the person actually has HIV. This would happen if their body has not started producing the markers of HIV infection at levels that are detectable by the test. When a test result is negative after a recent exposure to HIV, the person should be retested at the end of the window period to confirm they are HIV negative.

The most commonly used HIV tests in Canada detect different markers of HIV infection. Some look for HIV antibodies (proteins produced by the body's immune system in response to HIV infection) only, while another looks for both antibodies and the p24 antigen (a specific part of the virus itself). All antibody tests in Canada can detect both HIV-1 (the most common type of HIV) and HIV-2.

Rapid HIV screening tests, including both the POC and self-test, are third-generation tests and detect HIV antibodies. The window period for these tests is between three weeks and 12 weeks. These tests can detect HIV antibodies in 50% of people by about 22 days after exposure to HIV and 99% of people by 12 weeks after exposure.

The antibody–antigen combination test is the fourth-generation screening test used in public health laboratories in Canada. This test detects both the p24 antigen and antibodies. The window period for this test is between two weeks and 6.5 weeks. It can detect HIV in 50% of people by 18 days after exposure to HIV and in 99% of people by 44 days after exposure. This means that the fourth-generation test can find an infection at least a week earlier than third-generation POC and self-tests in most people. This is because the p24 antigen is detectable before HIV antibodies. In addition, the fourth-generation test can rule out an HIV infection 5.5 weeks earlier than third-generation tests.

Most people will get an accurate test result with third- or fourth-generation tests three to four weeks after an exposure to HIV. However, not everyone will. It's important to test again at the end of the window period to rule out an HIV infection.

The Geenius confirmatory 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.

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.

Sensitivity and specificity

Sensitivity and specificity are measures of the accuracy of an HIV test.

Sensitivity is the chance that a positive test result will correctly indicate that a person has HIV. This means that if the person has HIV, the test will detect it. Higher sensitivity means there is a lower chance of a false-negative result (testing negative when actually HIV positive).

Specificity is the chance that a negative test result will correctly indicate that a person does not have HIV. This means that 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 (testing positive when actually HIV negative).

HIV screening tests used in Canada (including third- and fourth-generation tests) all have a sensitivity of up to 99.9%. In other words, if 1,000 HIV-positive people were tested for HIV, 999 would correctly test positive and one would incorrectly test negative. High sensitivity is ideal for a screening test because it effectively rules out people who don't have HIV (as long as they are outside the window period). 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.

HIV screening tests used in Canada have a slightly lower specificity of up to 99.5%. In other words, if 1,000 HIV-negative people were tested, 995 would correctly test negative and five would incorrectly test positive. Since the specificity is lower, this means there is a higher chance of false positives with the screening tests. This is why all positive screening test results are sent for confirmatory testing with a test that has a very high specificity.

The Geenius assay has a specificity of 100%. This means that the chance of a false-positive result after confirmatory testing is essentially zero.

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Production of this document has been made possible through a financial contribution from the Public Health Agency of Canada. The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada.

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