/ COURSE CONTENT

HIV and Hepatitis C Testing

In-depth knowledge of testing technologies, approaches to testing, and how all service providers play an important role in reaching people with HIV and hepatitis C.

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UNIT ONE

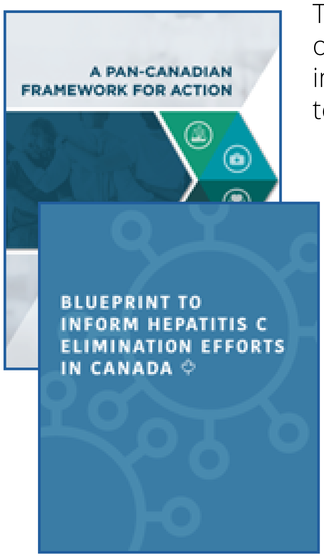
Introduction to Testing

At the end of this unit, you will be able to:

1. *Explain why testing is important.*
2. *Recognize the range of barriers and facilitators to HIV or hepatitis C testing.*
3. *Describe testing approaches for reaching people with undiagnosed HIV or chronic hepatitis C.*
4. *Identify clinical indications and priority populations for HIV or hepatitis C testing.*

Global targets to reach the undiagnosed

In Canada, according to the most recent estimates, 13% of people living with HIV (in 2018) and 44% of people with chronic hepatitis C infection (in 2011) were unaware of their status. Canada has signed on to global targets to eliminate HIV and hepatitis C as public health threats by 2030. These targets include ambitious goals for reaching people who are undiagnosed.



A PAN-CANADIAN FRAMEWORK FOR ACTION

BLUEPRINT TO INFORM HEPATITIS C ELIMINATION EFFORTS IN CANADA

The **Pan-Canadian STBBI Framework for Action**, developed by the Public Health Agency of Canada, provides a guide for supporting action to achieve global targets to reduce the impact of Sexually Transmitted and Blood-Borne Infections (STBBI) through prevention, testing, care and treatment. This includes both HIV and hepatitis C.

The **Blueprint to inform hepatitis C elimination efforts in Canada** outlines specific targets in the Canadian context to align with global elimination goals for hepatitis C and to complement the Pan-Canadian STBBI Framework for Action. The Blueprint aims to guide actions and strategies by policy makers, program planners and service providers to address hepatitis C infection through prevention, testing and treatment. The Blueprint target is to diagnose 70% of all people with hepatitis C by 2025 and 90% by 2030.

In order to eliminate HIV and hepatitis C as public health threats, we all have a role to play in increasing access to testing and treatment within our communities.

Getting tested is important for a person's health

It is common for people with HIV and/or hepatitis C to not experience any obvious symptoms for many years, even though the virus is active and affecting their body. For example, a person can have hepatitis C for 20 to 30 years without any symptoms. This makes it more difficult to ensure that people are diagnosed early.

Both HIV and hepatitis C can have serious health implications if someone is undiagnosed, leading to increased morbidity and mortality. Testing is the only way to know for sure if a person has HIV or hepatitis C.

Because of the shared routes of transmission, it is important that some people be tested for both HIV and hepatitis C and that those diagnosed with either HIV or hepatitis C be tested for the other virus and provided with appropriate prevention counselling. Testing for other STBBIs may also be an appropriate consideration.

If a person regularly participates in activities that increase their chances of getting HIV and/or hepatitis C, regular testing is necessary to know their current HIV or hepatitis C status. Frequent testing allows new infections to be diagnosed and referred to care early. It also provides ongoing opportunities to discuss HIV and hepatitis C prevention options.

Testing and diagnosis for HIV and/or hepatitis C provides people with information to make informed decisions about their health. When a person is diagnosed with HIV and/or hepatitis C, they can access treatment, care and other supports to improve their health and prevent transmission to their contacts who may be at risk of being exposed (e.g., sexual and/or drug use partners and infants born to people with HIV and/or hepatitis C).

Benefits of early detection

Early detection can lead to better health outcomes for people diagnosed with HIV and/or hepatitis C. HIV is treatable and hepatitis C is curable, but the only way to access the necessary treatment, care and support is to first be diagnosed.

Untreated chronic hepatitis C can cause inflammation and scarring of the liver over time, sometimes leading to severe liver injury (cirrhosis) or even cancer. The common lack of symptoms makes it less likely for hepatitis C to be diagnosed soon after infection, but early diagnosis and treatment will prevent long-term liver health complications for most people. We now have very effective treatments that can cure more than 95% of people with hepatitis C within eight or 12 weeks.

Untreated HIV infection weakens the immune system, making a person vulnerable to infections, diseases and certain cancers. Untreated HIV also keeps the immune system activated, resulting in chronic inflammation that can injure vital organs and systems over time. With early diagnosis and treatment, most people with HIV can avoid long-term complications, stay healthy and live a long, full life.

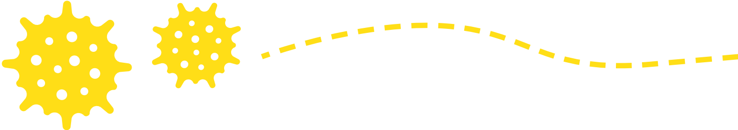
There are also prevention benefits because early detection followed by engagement in care and successful treatment can stop further transmission of both HIV and hepatitis C. A person who is cured of hepatitis C can no longer pass the virus to others. (However, they can become re-infected if they are exposed to the virus again.) When a person living with HIV takes successful ongoing treatment to maintain an undetectable viral load, their chance of passing HIV to others is dramatically reduced through all routes of transmission. In fact, a person living with HIV who is on successful treatment can't pass HIV on to their sex partners.

Treatment can prevent transmission between individuals and it also reduces transmission at the community level. Treatment of individuals living with HIV and hepatitis C lowers the amount of virus circulating in the community, which reduces the chance of someone coming into contact with these viruses. This contributes to reduced transmission in the community overall.

Testing is the gateway to treatment and prevention

Testing and diagnosis are the gateway to engagement in treatment, care and support for people with HIV and/or hepatitis C. Newly diagnosed people need to be actively referred and connected to comprehensive care, treatment and other supports in their community.

Testing is also the gateway to prevention services for people who have an ongoing chance of transmission. Prevention services and supports might include harm reduction programs, HIV pre-exposure prophylaxis (PrEP), and engagement in regular screening for HIV, hepatitis C and other STBBIs.



Barriers can exist at multiple levels

It is important to recognize that a person can experience barriers that can make it challenging to access HIV and/or hepatitis C testing. We must overcome barriers to testing in order to reach and support those individuals who may be undiagnosed.

Barriers to accessing testing can exist at different levels. We can distinguish between two broad categories: barriers at the individual level and barriers at the system level.

Individual-level barriers relate to the service provider or person seeking care.

System-level barriers are caused by the structure of the healthcare system or services.

Examples of barriers to testing

Examples of individual-level barriers to testing that have to do with the person seeking care can include:

- fear that testing will not be confidential
- fear that testing positive will lead to social repercussions such as stigma and discrimination
- lack of knowledge about HIV or hepatitis C and their risk of exposure

Examples of individual-level barriers to testing that have to do with a service provider can include:

- lack of knowledge about who should get tested, when to offer a test, and how to provide pre- and post-test counselling
- not providing culturally safe care in working with priority populations
- provider discomfort and/or perceived patient discomfort in talking about past or current risk behaviours
- competing priorities (e.g., not enough time)

System-level barriers to testing include the availability and complexity of testing services, for example:

- when testing services have limited operating hours, long wait times or limited language options, it can be difficult for some clients to access testing services
- when a person has to attend multiple appointments in order to get a diagnosis, they can become lost to follow-up, thus not receiving their test result and/or not getting connected to care

Many people at risk for HIV and/or hepatitis C are not adequately engaged or served by mainstream health services, including: people who use drugs; Indigenous peoples; gay, bisexual and other men who have sex with men (gbMSM); immigrants and newcomers. This means they are also more likely to experience barriers to accessing HIV and/or hepatitis C services. Programs and service providers can offer testing in ways that facilitate access to testing and address common barriers.

Approaches to testing

What approaches are used to reach people who may be undiagnosed for HIV and/or hepatitis C testing? First, there are clinical indications for when a person should be tested for HIV or hepatitis C—for example, if they show symptoms of early HIV or hepatitis C infection.

Let's review these symptoms...

Review: Symptoms of HIV and hepatitis C

The majority of people do not experience any early hepatitis C symptoms and many people do not have symptoms of recent HIV infection. Within two to four weeks after HIV infection, flu-like symptoms can occur, such as fatigue, fever, sore throat, swollen lymph nodes, headache, loss of appetite and rash. After hepatitis C infection, some people may experience symptoms such as fatigue, decreased appetite, fever, nausea, muscle aches and jaundice (yellowing of the skin and whites of the eyes).

For both HIV and hepatitis C, early symptoms only appear for a short time. Any individual who presents with these symptoms and has had a potential exposure should be offered a test to determine if symptoms are the result of HIV and/or hepatitis C infection or something else.

In addition to symptoms of recent infection, clinical indications of a chronic infection with HIV or hepatitis C should also prompt the offer of a test. For HIV, these can include indications such as an AIDS-defining illness or unexplained weight loss. For hepatitis C, these can include indications such as raised liver enzyme levels and unexplained chronic liver disease.

Other than clinical indications, we can use a variety of testing approaches to help reach people with undiagnosed HIV and/or hepatitis C. In general, different strategies will be more or less effective depending on the population, and some populations will be harder to reach.

In addition to being offered a test by a provider, individuals can also request HIV and hepatitis C testing. If a person thinks they may have acquired HIV or hepatitis C or may be at risk, they can ask a healthcare provider for a test.

Approaches to HIV testing

There are two broad approaches to HIV testing: targeted and routine.

Targeted testing aims to identify and reach people with an increased chance of acquiring HIV, whether based on behavioural, clinical or demographic characteristics.

Routine testing aims to offer testing to patients during healthcare visits regardless of known risk factors or symptoms.

Targeted testing approaches can be effective at reaching people who may be undiagnosed because they focus on groups with higher rates of HIV and on identifying people within those groups who may have high-risk exposures to HIV.

A routine approach to testing is effective because healthcare providers may not perceive a risk or recognize a person to be at risk for HIV. In addition, an individual may not disclose their reasons for testing or their risks for HIV. Routine testing helps to identify people with HIV who are not reached through targeted testing approaches.

Review: How can a person get HIV?

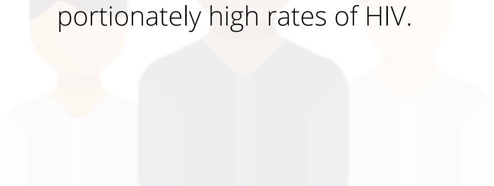
HIV can be passed through five body fluids: blood, semen (including pre-cum), rectal fluid, vaginal fluid and breast milk.

There are a limited number of activities that can transmit HIV. These include:

- *sexual activities (such as vaginal and anal sex)*
- *sharing needles or other equipment to inject drugs*
- *sharing body work equipment (such as needles and/or ink for tattooing and piercing)*

HIV can also be transmitted to a fetus or infant through pregnancy, childbirth and breastfeeding if the person carrying the child is HIV positive.

Targeted HIV testing



Targeted HIV testing aims to reach people who participate in activities that put them at ongoing risk for HIV, such as having unprotected sex with partners of unknown HIV status or sharing drug use equipment. Targeted testing focuses on engaging certain populations that have disproportionately high rates of HIV.

The priority populations that are disproportionately affected by HIV in Canada include:

- gay, bisexual and other men who have sex with men (gbMSM)
- people who use injection drugs
- indigenous peoples (First Nations, Inuit, Métis)
- people from countries where there is a high prevalence of HIV

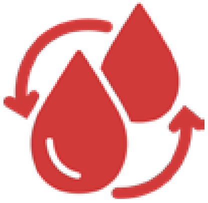
It is important to understand that while certain populations have higher rates of HIV overall, this does not mean that being a member of one of these populations is a "risk factor" for getting HIV in and of itself.

Some examples of targeted HIV testing programs include:

- an Indigenous health centre offering HIV testing at their community health events
- offering HIV testing on a mobile van that distributes new drug use equipment to people who use drugs
- setting up an HIV testing clinic at a bath house attended by gbMSM

Targeted approaches can use strategies to help address barriers to testing, such as:

- **Offering peer-based testing during outreach to priority populations.** Bringing point-of care testing to where people are and using peers (with shared life experiences) to administer testing can build trust among clients, reduce anxiety about testing, and help to normalize HIV testing.
- **Providing HIV education to clients who belong to priority populations or who otherwise have an increased chance of acquiring HIV.** Education about HIV transmission, the benefits of early diagnosis and the effectiveness of treatment may help to address individual-level barriers such as lack of perceived risk or fears of getting tested/diagnosed.



It is important to encourage people to get tested on a regular basis if they participate in activities that increase their chance of getting HIV, such as sharing injection drug use equipment or having unprotected sex with partners of unknown HIV status. National guidelines developed by the Public Health Agency of Canada recommend that HIV testing should be offered at least annually for people at ongoing risk for HIV; however, provincial guidelines may vary.

Routine HIV testing

Canadian HIV testing guidelines also recommend routine testing. They suggest that HIV testing should be offered periodically during routine medical appointments. Some provincial guidelines also recommend routine HIV testing in doctors' offices and hospitals.

Routine testing can help to address barriers to testing such as:

- **Lack of knowledge about HIV among healthcare providers and patients.** Routine testing can help find people with undiagnosed HIV who don't fit a typical risk profile or who don't disclose their risk behaviours. Research shows that many people who are diagnosed with HIV late had missed opportunities for earlier diagnosis in healthcare settings but were not identified by healthcare providers or did not identify themselves as needing HIV testing.
- **HIV stigma.** Routinely offering HIV testing can normalize HIV testing in the general population and help reduce stigma.

Some examples of routine HIV testing include:

- a healthcare provider offering an HIV test to all of their adult patients every five years
- an emergency department offering an HIV test to patients
- offering an HIV test to all pregnant people during prenatal care—this happens in all provinces and territories

In order to maximize the effectiveness of a routine testing approach:

- healthcare providers need to be familiar with testing guidelines and recommendations for when to offer testing
- organizations that provide testing should implement policies that facilitate HIV testing, such as training for staff on how/when to offer testing and using prompts such as posters in the examination room or alerts in electronic medical records

Routine HIV testing may be opt-in or opt-out. For opt-in testing, a person is offered a test and must actively accept before the test can occur. For opt-out testing, a person is notified that HIV testing is a part of normal care for everyone but they can decline. If they don't decline, consent to testing is assumed. Different provinces use different approaches to routine testing.

Approaches to hepatitis C testing

For hepatitis C, different testing strategies can be used depending on the population. Two broad approaches to hepatitis C testing are risk-based testing and one-time testing.

Risk-based testing involves reaching people with an increased chance of acquiring hepatitis C, whether based on behavioural, clinical or demographic characteristics. This is the main recommended approach in Canada.

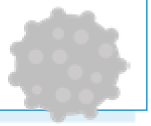
In recent years, **one-time testing** of people born between 1945 and 1975 is also being recommended by the Canadian Association for the Study of the Liver and the Blueprint to inform hepatitis C elimination efforts in Canada, in order to identify more people with undiagnosed hepatitis C. One-time testing overcomes the issue of having to identify past risk exposures that may have occurred years or even decades prior in this birth cohort. However, there has been limited uptake of these recommendations in Canada.

Review: How can a person get hepatitis C?

Hepatitis C is passed through blood-to-blood contact. It can live outside of the body for many days.

There are a limited number of activities that can transmit hepatitis C. These include:

- *sharing needles or other equipment (e.g., cookers, filters, pipes) to inject, smoke or snort drugs*
- *sharing needles or other equipment for tattooing, piercing and acupuncture*
- *unsafe medical and dental practices (typically conducted in other countries) involving: the re-use of medical equipment (such as needles for vaccines); the*
- *use of equipment that was not properly sterilized; the receipt of blood, blood products or organ transplant that was not screened for hepatitis C*
- *sharing personal care items that might have blood on them (e.g., razors, nail clippers, toothbrushes)*
- *having anal sex without a condom, especially when blood is present or when one of the partners has HIV or another sexually transmitted infection*
- *being born to a mother with hepatitis C*



Risk-based hepatitis C testing

Risk-based hepatitis C testing aims to reach people who participate in activities that put them at ongoing risk for hepatitis C, such as unsafe drug use or tattooing practices, and people who may have been exposed to hepatitis C in the past.

For people who have ongoing risks for exposure to hepatitis C, regular ongoing testing is required. This includes people who have either cleared hepatitis C or have been cured of hepatitis C but continue to have an ongoing chance of re-exposure.

The priority populations that are disproportionately affected by hepatitis C in Canada include:

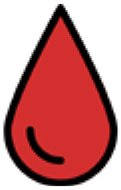
- people who inject drugs/people who use drugs
- Indigenous peoples (First Nations, Inuit, Métis)
- people with experience in the prison system
- immigrants and newcomers from countries where hepatitis C is common
- gay, bisexual and other men who have sex with men (gbMSM)

It is important to understand that while certain populations have higher rates of hepatitis C overall, this does not mean that being a member of one of these populations is a “risk factor” for getting hepatitis C in and of itself.

Some examples of a risk-based approach to hepatitis C testing include:

- integrating hepatitis C testing into an existing supervised injection service or overdose prevention site
- offering voluntary and confidential hepatitis C testing to incarcerated people at prison entry and regularly during prison stay
- providing hepatitis C testing yearly as part of routine testing for people who are on PrEP

Risk-based approaches can use strategies to help address barriers to testing, such as:

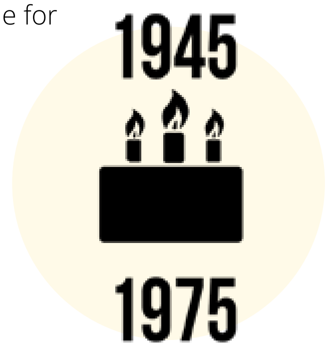


- **Using simpler and more flexible testing technologies** (e.g., point of care or dried blood spot testing) to reach people who might not otherwise access healthcare, in a variety of non-traditional settings. Using these technologies to bring outreach testing to priority populations can help address barriers to access for some individuals in priority populations.

- **Integrating hepatitis C testing into other services used by priority populations**, such as sexual health clinics offering STBBI testing, harm reduction programs, or Indigenous health care centres. This can help ensure that testing services are offered in a way that is culturally safe and accessible to the populations being served.

One-time testing for hepatitis C

As we’ve learned, a large proportion of people with chronic hepatitis C remain undiagnosed in Canada. This has led to consideration of other approaches to expand testing beyond those with known risk factors to reach more people who may not know they are at risk for hepatitis C.



In Canada, one-time hepatitis C testing is being recommended by one clinical guideline for all people born between 1945 and 1975, regardless of any reported risks. So far there has been limited uptake of this approach to hepatitis C testing.

The rationale for one-time testing in this birth cohort is that this group has a high hepatitis C prevalence but most people were exposed through medical procedures or past injection drug use and have no current chance of transmission. Testing and linkage to care can be life saving in this birth cohort, which also has the highest rates of hepatitis-related liver failure and liver cancer.

One-time testing may also be used to find undiagnosed hepatitis C infection in newcomers to Canada from countries where hepatitis C is common. Individuals may have been exposed through unsafe medical and dental practices in their home countries but are not aware of their risk for hepatitis C.

One-time testing can help to address barriers to testing such as:

- **Lack of knowledge about hepatitis C among healthcare providers and patients.** A one-time testing approach used across a large population can help to find people with undiagnosed hepatitis C who were exposed to hepatitis C a long time ago and don’t have a current or ongoing risk.

- **Hepatitis C stigma.** Systematically offering a hepatitis C test to everyone within the 1945 to 1975 birth cohort can help to normalize hepatitis C testing in the general population and help to reduce stigma.

Examples of the one-time hepatitis C testing approach include:

- a healthcare provider offering a hepatitis C test (once) to all their patients who were born between 1945 and 1975

- routinely offering voluntary hepatitis C testing and linkage to care to newcomers who are part of this birth cohort after arrival in Canada

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UNIT TWO

HIV Testing and Diagnosis

At the end of this unit, you will be able to:

1. *Explain the ways people get tested for HIV.*
2. *Describe the different technologies that are used to test for HIV in Canada.*
3. *Explain the meaning and importance of window periods.*
4. *Identify the window periods for HIV tests used in Canada.*
5. *Discuss the accuracy of HIV tests.*
6. *Explain what happens after an HIV-positive diagnosis.*

This unit will cover the different ways people can test for HIV and the steps involved in the HIV testing process.

Where and how does HIV testing happen?

To access an HIV test from a provider, people can voluntarily request a test or they may be offered a test by a provider without asking for it. In all cases, a person must give their consent before having an HIV test. People can also access the HIV self-testing kit approved for use in Canada by ordering directly from the manufacturer (bioLytical), or through purchase at a local pharmacy that stocks it.

Testing practices vary across the country. Each province and territory in Canada determines how and where HIV testing can happen, which includes:

- the availability of testing in different settings
- how the tests are conducted and by whom
- which testing technologies are widely available
- what personal information is collected

In Canada, HIV testing is usually initiated in a healthcare provider's office, but it can also happen in a variety of healthcare and community-based settings such as hospitals, public health clinics, sexual health clinics, health centres, pharmacies, and mobile vans or other outreach settings. The availability of testing in settings outside of healthcare provider offices varies by province/territory.

All HIV tests used in Canada require a blood sample. Blood may be collected on site or at a local laboratory. Tests using oral fluid are not currently available in Canada.

Most commonly, a blood sample is drawn from a person's vein and sent to a laboratory for analysis. However, other less common approaches to testing are also available in some provinces and territories:

- An HIV rapid point-of-care test allows for a blood sample to be taken from a finger prick and tested immediately onsite with the result available within a few minutes.
- A finger prick blood sample can be collected as blood spots on a card (called Dried Blood Spot testing) and sent to a laboratory for analysis.

HIV self-testing is now also an option in Canada. The HIV self-test allows people to test themselves for HIV in their home or other locations using a single drop of blood from a finger prick.

HIV diagnosis requires a two-step testing process

There are usually two steps in the testing process required to diagnose an HIV infection. Depending on the type of testing, a person may only need to give one blood sample.

The first test is called a **screening test**.

If a screening test result is **non-reactive** (i.e., negative), this means the person who was tested does not have HIV, as long as they have not had a recent exposure to HIV. However, if the person has had a recent exposure to HIV they should be advised to get tested again, up to three months (i.e., the maximum window period) after their most recent exposure to confirm the negative result.

If the screening result is **reactive**, this means the person who was tested is likely HIV positive but the result needs to be confirmed. The screening test is not diagnostic, so a person is never diagnosed with an HIV infection based on a reactive result from a screening test.

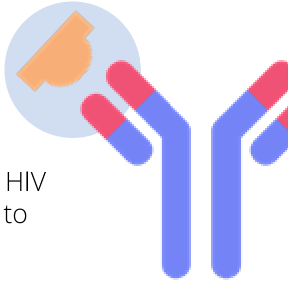
The second test, which is called a **confirmatory test**, is used to confirm a reactive screening test result. If the confirmatory test is also reactive, a person is confirmed to be HIV positive.

Standard HIV testing

The majority of blood samples for HIV testing are analyzed in a laboratory. This is known as **standard HIV testing**. To test for HIV, blood is drawn from a person's vein and sent to a public health laboratory for testing. This is the kind of testing that would generally be initiated by a healthcare provider such as a doctor or nurse. The person being tested may be asked to return for a second visit once the result is available (usually one to two weeks later) or they may receive their result over the phone or online if the result is negative.

Standard HIV testing – Screening test

In Canadian public health laboratories, blood samples are **screened** for HIV using a **fourth-generation HIV test**. This test is also known as an antigen-antibody combination test because it detects the p24 antigen (a protein inside the virus) and HIV antibodies (proteins produced by the body to fight HIV infection).



When a laboratory screening test has a non-reactive result, no further testing is done on that sample. If the test shows that a person may have HIV (a reactive test result), then a confirmatory test is automatically done on the same sample.

Standard HIV testing – Confirmatory test

The **confirmatory** test used in Canada is called the **Geenius HIV 1/2 Confirmatory Assay**. This test detects antibodies to HIV-1 and HIV-2 but does not directly detect the virus. Other types of confirmatory testing may be used in certain circumstances, such as when a test result is indeterminate. These include the nucleic acid amplification test (NAAT), which detects genetic material of the virus, and p24 antigen-only tests.

When the laboratory testing is complete (with one or more tests, as required), a non-reactive screening test is reported back to the tester as an HIV-negative result. An HIV-positive diagnosis is made only after a confirmatory test indicates that a person has HIV. The reactive confirmatory test is reported back to the tester as an HIV-positive result.

Dried Blood Spot Testing

Dried blood spot (DBS) testing is another way to take a blood sample for standard testing in a laboratory. DBS uses blood from a finger prick that is collected as blots on a paper card and dried at room temperature. The card is then mailed to a public health laboratory for screening with a fourth-generation test and confirmatory testing using the Geenius HIV 1/2 Confirmatory Assay (if the screening test is reactive). Very few laboratories in Canada are currently able to process DBS cards.

HIV Point-of- care (POC) testing

HIV point-of-care (POC) testing is a rapid test that allows HIV **screening** to happen at the location where blood is taken. These tests require only a drop of blood from a finger prick to test for HIV and the person being tested will get their screening result within a few minutes.

The only HIV POC test currently approved in Canada is called the INSTI Rapid Antibody Test. This screening test is known as a **third-generation HIV test** because it only detects HIV antibodies, unlike the fourth-generation tests used in standard HIV testing that look for both HIV antibodies and the p24 antigen.

If the HIV POC test result is non-reactive (negative), no further testing is performed and the person who was tested will be told their result on the spot. However, if the person has had a recent exposure to HIV they should be advised to get tested again, up to three months after their most recent exposure to confirm the negative result. If a person is at ongoing risk they should be counselled to test frequently for HIV.

If an HIV POC test result is reactive (meaning, a preliminary positive result), it needs to be confirmed by a laboratory test. The person who was tested will need to have a blood sample drawn from their vein and sent to a public health laboratory for testing to confirm the reactive result. An HIV-positive diagnosis is made only after a confirmatory test performed in a lab indicates that a person has HIV.

HIV POC testing is not available in all provinces and territories. Where it is used, it is generally only available in a limited number of specified community locations.

Self-testing

The **HIV self-test** available in Canada is a third-generation screening test that uses the same technology as the HIV POC test so it only detects HIV antibodies. A person who gets a reactive result using a self-test will need to access standard HIV testing to confirm their result.

What is the window period?

No test can detect HIV immediately after infection. It's important to understand the concept of the **window period** to know when someone should test for HIV to get the most accurate result.

The **window period** is the time between when a person has been exposed to HIV and when a test can tell they have HIV. The window period can vary between 2 weeks and 3 months. The length of the window period varies from person to person and the type of test used. Some people develop markers of HIV infection that are detected by HIV tests (the p24 antigen and antibodies) slowly and some people develop them more rapidly. Once these markers of infection are present in amounts that the test can detect, the window period is over. Therefore, if at any time a person gets a positive result from a confirmatory test for HIV it means the window period is over and the person has HIV.

If someone has had a recent exposure to HIV and gets tested for HIV during the window period, the test may come back as negative (non-reactive) despite the person actually having HIV. This would happen if their body has not started producing the p24 antigen or antibodies at levels that are detectable by a 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. Some provinces recommend testing at intervals until the end of the window period to pick up HIV infection as early as possible.

What are the window periods for screening tests used in Canada?

The window period varies for each type of test and depends on whether the test is looking for antibodies only (third-generation tests) or both p24 antigen and antibodies (fourth-generation tests).

For the third-generation screening tests that detect only HIV antibodies (the HIV POC test and the self-test) the window period is between 3 weeks and 12 weeks. This test 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.

For the fourth-generation test that detects both the p24 antigen and HIV antibodies the window period is between 2 weeks and 6.5 weeks. This test 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 fourth-generation tests can find an infection at least a week earlier than third-generation tests in most people. This is because p24 antigen is detectable before HIV antibodies. In addition, fourth-generation tests can rule out HIV infection 5.5 weeks earlier than antibody-only tests.

How does the window period impact HIV testing?

In Canada, most people will get an accurate test result, with a third- or fourth-generation test, three to four weeks after a potential exposure to HIV; however, not everyone will. That's why it's important to test again at the end of the window period in order to rule out an HIV infection. The end of the window period is 12 weeks after a potential exposure for third-generation tests and 6.5 weeks after a potential exposure for fourth-generation tests. Provinces and territories may have their own recommendations for frequency and timing of testing.

A person who gets tested for HIV may be concerned about a specific recent exposure. In this case, taking an HIV test at multiple points during the window period (for example, at 3 weeks and 6 weeks) can increase the chance of detecting a new infection early. The further into the window period, the more likely it is that the test will be able to correctly identify if the person has HIV. However, if these tests are negative, a final test at the end of the window period for the test can rule out an HIV infection from that specific exposure.

In another scenario, a person may have ongoing potential exposures to HIV. In this case, it is best to get tested for HIV every three months. A non-reactive (negative) test result means that the person was definitely HIV-negative three months ago, but their status may have changed since then. Regular testing at three-month intervals will help detect HIV early in this scenario.

Example

Let's look at an example to help illustrate the window period. A man has unprotected anal sex on one occasion and is worried that he may have been exposed to HIV. Three weeks later, he visits a sexual health clinic and has blood drawn to get tested for HIV with a fourth-generation test. The result comes back positive. In this case, it was beneficial for this person to get tested early because their body was already producing levels of antibodies and/or the p24 antigen that could be detected by a fourth-generation laboratory test. If the test result had been negative, it would be important for this person to get tested again because at three weeks post-exposure they were still within the window period.

However, let's say this same man starts having unprotected anal sex on a regular basis. He should be tested for HIV regularly, until three months after his last potential exposure to HIV to rule out HIV infection.

Accuracy of HIV tests

All HIV tests are very accurate when markers of HIV infection are present in the blood.

Screening tests are very good at detecting true negative results but positive results need to be confirmed. Once confirmatory testing has been done, the chance of a positive result being false is essentially zero.

Understanding sensitivity and specificity

The accuracy of HIV tests is explained using the concepts of sensitivity and specificity. The higher the sensitivity and specificity, the more accurate the test.

Sensitivity is the chance that a positive test result will correctly identify that a person has HIV. Meaning, 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. Meaning, if the person does not have HIV, the test will be negative. Higher specificity means there is a lower chance of a false-positive result (testing positive when actually HIV negative).

Accuracy of tests used in Canada

HIV screening tests used in Canada (including the laboratory test, the POC test and the self-test) 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).

Screening tests 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, used for all confirmatory testing, has a specificity of up to 100%. This means that the chance of a false-positive result after confirmatory testing is close to zero.

Although rare, false positives are mostly a concern with HIV POC testing and self-testing. This is because a reactive result for one of these tests always needs to be confirmed and there will be a delay between getting a preliminary positive result and getting a confirmatory test result (which can take one to two weeks from time of testing). If a truly HIV-negative person has a reactive (false positive) result, this can cause undue anxiety and stress while they wait (one to two weeks) for confirmatory testing.

What happens after an HIV-positive diagnosis?

After an HIV-positive diagnosis several things should happen. First, newly diagnosed people need to be referred to care and treatment and any other supports they may need. Additionally, after a person receives an HIV-positive diagnosis, the positive result is reported to public health. This initiates a process of partner notification which helps to identify other people who may benefit from testing (e.g., sexual and/or drug use partners) to prevent onward HIV transmission.

Public Health notification, reporting and data collection

An HIV-positive diagnosis is reported to public health authorities because it is considered to be of significant importance to public health. When an HIV infection is confirmed, it is reported to the provincial or territorial public health authorities where the test was done.

The amount and type of information that is collected and shared with public health depends on the province or territory where the test was done. However, all provinces and territories provide non-identifying data on positive HIV tests to the Public Health Agency of Canada for national-level reporting on HIV in Canada.

When someone takes an HIV test, some of their non-identifying personal information may be collected. This may include their age, sex, city of residence, country of birth, ethnicity and their HIV-related risk factors.

Whether or not a person's name and personal information gets recorded depends on the testing option: nominal (name-based), non-nominal (non-identifying) or anonymous testing.

Nominal testing (or name-based testing) is available across Canada. The HIV test is ordered using the person's name, the result is reported to public health using the person's name, and the test result is recorded in the person's healthcare record.

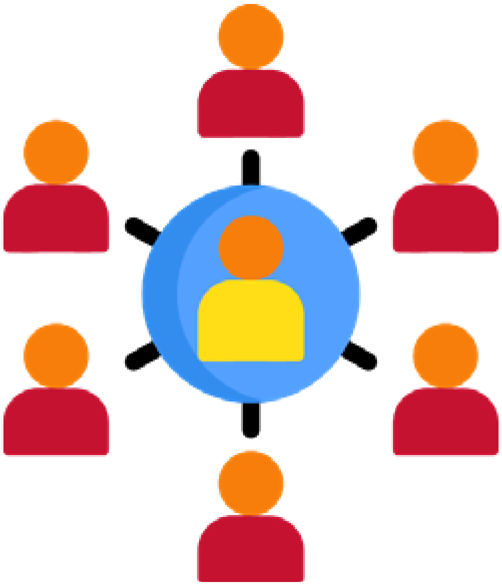
Non-nominal testing is also available across Canada. The HIV test is ordered using the person's initials or a code or alias (depending on the province/territory), but not their full name. In most provinces/territories, if the test is positive, the result is reported to public health using the person's name. The test result is also recorded in the healthcare record of the person being tested.

Anonymous testing is available in some provinces and territories. The person does not have to give their name and the HIV test is carried out using a code that is not linked to their identity. In most provinces/territories, if an anonymous test is positive, public health will be notified but the name of the person being tested is not shared (as it is not known). The HIV test result is not recorded on the healthcare record of the person being tested.

Partner notification

HIV partner notification, also called contact tracing, is the practice of identifying, locating and informing someone that a partner they have had sex or shared drug use equipment with has been diagnosed with HIV. This is meant to encourage partners/contacts to test for HIV in the hopes of identifying new HIV infections as early as possible.

When someone has a confirmed HIV diagnosis, they will be asked to contact or provide contact information for all of their contacts who may have been exposed. If the person chooses to not contact their partners themselves, a public health nurse or other healthcare provider will attempt to contact partners and encourage them to test for HIV.



While the public health nurse or other healthcare provider does not disclose the name of the person who tested positive, partners may figure out who it is. While all efforts are made to protect the person's anonymity, this may not always be possible (for example, if the person being contacted has only had one sexual partner).

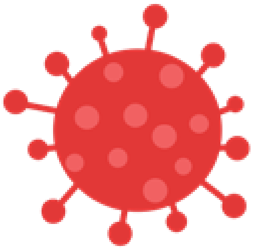
Public health in all provinces and territories carry out partner notification; however, depending on the province/territory, there are different laws and/or policies regarding this practice.

Linkage to HIV care, treatment and other services

HIV testing is an important entry point for people into services such as HIV care, treatment and prevention, but can also help connect people to social supports such as harm reduction and housing. Counselling should be provided to all individuals after an HIV test, regardless of the result. Every testing encounter provides an opportunity to share information about HIV and discuss/provide referrals to appropriate supports.

For people who test HIV positive, attempts should be made to ensure that they are linked to, engaged in and retained in HIV care and treatment. They should also be linked to information and services related to HIV prevention to help prevent passing HIV to others.

It is important for service providers to help address issues related to the social determinants of health with their clients. Service providers may need to connect clients to other services and providers to help address identified issues, for example mental health services, substance use treatment, and/or housing programs.



For people who test negative but may continue to be at risk of acquiring HIV, attempts should be made to ensure that they are linked to prevention services, such as pre-exposure prophylaxis (PrEP), risk reduction counselling and ongoing routine testing.

In another unit, we explore tips and tools for supporting client linkage to care, treatment and other supports.

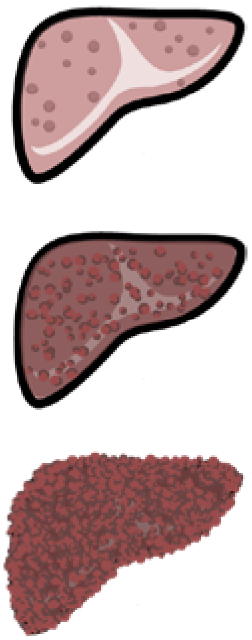
UNIT THREE

3 Hepatitis C Testing and Diagnosis

At the end of this unit, you will be able to:

1. *Explain the two-step testing process for diagnosing hepatitis C.*
2. *Identify the ways people get tested for hepatitis C.*
3. *Describe the different technologies used to test for hepatitis C in Canada.*
4. *Explain the meaning and importance of window periods.*
5. *Discuss the accuracy of hepatitis C tests.*
6. *Explain what happens after a hepatitis C diagnosis.*

This unit will cover the different ways to get tested for hepatitis C and the steps involved in the hepatitis C testing process.



Review: What is the cycle of a hepatitis C infection?

First, let's review a few key points about hepatitis C that are relevant to testing.

Hepatitis C is contracted when the hepatitis C virus gets into the blood. Once in the blood, the virus infects the liver. The virus uses cells in the liver to make copies of itself and cause an infection.

The first six months of hepatitis C infection is called **acute infection**. For some people who get hepatitis C, the virus goes away on its own within these first six months of infection. This is called **spontaneous clearance**. About 1 in 4 people will spontaneously clear hepatitis C during the acute phase. For about 3 out of 4 people, the virus remains in the body after six months. At this point, hepatitis C will not go away on its own. This is called **chronic infection**. A person with chronic hepatitis C infection will need treatment to be cured of hepatitis C.

Review: Antibodies to hepatitis C virus and re-infection

During hepatitis C infection, the immune system produces **antibodies** to fight the hepatitis C virus. A person will have hepatitis C antibodies for the rest of their life, even after they are cured or if they spontaneously clear the virus. Antibodies do not make a person immune to hepatitis C re-infection. A person can still get hepatitis C again if they are exposed to the virus again.

Overview of the two-step testing process

There are usually two steps in the testing process required to diagnose a hepatitis C infection.

1. The first test is a **screening test**, or an antibody test. This test detects antibodies to determine if a person has ever had hepatitis C infection.
2. The second test is a **confirmatory test**, which is usually an RNA test (RNA stands for ribonucleic acid). This test detects genetic material of the virus to determine if a person currently has a hepatitis C infection.

There are a few situations where it is recommended to only offer the confirmatory test and not to do a screening test. The most common situation is for people who are being tested for hepatitis C re-infection. Anyone who has ever had a positive antibody test will test positive for hepatitis C antibodies for life and repeating this test does not provide any new information.

Where and how does hepatitis C testing happen?

To access hepatitis C testing from a provider, people can voluntarily request a test or they may be offered a test by a provider without asking for it. In Canada, the majority of hepatitis C testing is initiated in a healthcare provider's office, but it can also happen in a variety of healthcare and community-based settings, such as hospitals, public health clinics, prisons, health centres, pharmacies and mobile vans or other outreach settings.

All hepatitis C tests used in Canada require a blood sample. Blood may be collected where you receive health care or you may be asked to go to a local laboratory. Tests using oral fluid exist but are not currently available in Canada.

Testing practices vary across the country. Each province or territory in Canada determines the testing pathway for hepatitis C diagnosis, which includes:

- the availability of testing in different settings,
- how the tests are conducted and by whom,
- which testing technologies are widely available,
- what personal information is collected, and,
- how the blood samples are processed in the laboratory.

Most commonly, a blood sample is drawn from a person's vein and sent to a public health laboratory for hepatitis C screening and confirmatory testing.

Alternative (and less common) approaches to testing are also available in some provinces and territories.

- A hepatitis C **rapid** or **point-of-care (POC)** test is a screening test that allows for a blood sample to be taken from a finger prick and tested immediately onsite. A person can be told their test result in about 20 to 40 minutes.
- **Dried blood spot (DBS)** testing is when a blood sample is collected from a finger prick, dried on a paper card and sent to a laboratory for analysis. This type of test can be used for both screening and confirmatory testing.

Hepatitis C self-testing is not available in Canada. In some countries, hepatitis C self-testing is available for people to test themselves in their home or other locations using oral fluid or blood droplets from a finger prick.

Laboratory testing

The majority of blood samples for hepatitis C testing are analyzed in a laboratory. This is known as standard hepatitis C testing.

To test for hepatitis C, blood is drawn from a person's vein and sent to a public health laboratory. This is the kind of testing that would generally be initiated by a healthcare provider such as a doctor or a nurse.

Recall that the process for confirming a hepatitis C infection usually involves two tests—a screening test and confirmatory test.

- In some jurisdictions in Canada (at least seven provinces and territories), both the screening and confirmatory tests can be done from one blood sample. This is known as **reflex testing**.

- In other jurisdictions however, a person would need to provide one blood sample for a screening test and then return to provide a second blood sample for the confirmatory test.

- Reflex testing can help ensure that confirmatory testing happens when needed because otherwise there is a chance of people not coming back for confirmatory testing after a positive screening test.

This is an area that is evolving. An increasing number of public health laboratories are incorporating reflex testing in an effort to simplify the hepatitis C testing process.

Screening Test

In places where reflex testing does not happen, when a person requests or is offered a hepatitis C test, only a screening test will be done as the first step. The **screening test** is an antibody test called an **enzyme immunoassay (EIA)**. It detects the presence of hepatitis C antibodies in the blood.

The antibody test alone cannot tell whether the person has a current hepatitis C infection. A person will test positive for hepatitis C antibodies if they currently have hepatitis C but also if they had a hepatitis C infection in the past and spontaneously cleared the virus or were treated and cured.

When the screening test is done in a public health laboratory, the test provider will be contacted by the laboratory about the result in about one to two weeks. The provider will then be able to communicate the result to the person who was tested.

A **non-reactive** (negative) screening test result indicates that a person does not have hepatitis C antibodies and has never had a hepatitis C infection. No further testing is usually performed.

If the antibody test is **reactive** (positive), this means that the person has antibodies to hepatitis C and therefore has had a hepatitis C infection at some point in their life. A confirmatory test needs to be done to determine if a person currently has a hepatitis C infection (or whether it was cleared in the acute phase or with treatment).

Confirmatory Test

The confirmatory test detects the hepatitis C virus itself. The confirmatory test is often an RNA test. However, some jurisdictions also use another type of confirmatory test called a **core antigen test**.

The standard confirmatory test in Canada is the **RNA test**, or the “HCV RNA polymerase chain reaction (PCR) test.” This is a nucleic acid amplification test (also known as NAAT), which looks for the genetic material of the virus in the blood.

Another less common approach to confirmatory testing is an HCV core antigen test. This is an enzyme immunoassay test that detects HCV core antigen, which is a protein that is part of the hepatitis C virus.

Sometimes a person will only receive a confirmatory test. This includes if they are being tested for hepatitis C re-infection.

If a confirmatory test is **non-reactive** (negative), the person does not have a current hepatitis C infection.

A non-reactive confirmatory test after a reactive screening test means that the person no longer has hepatitis C (for example, due to spontaneous clearance or cure through hepatitis C treatment) even though they will always have antibodies in their blood.

If a person has a **reactive** (positive) confirmatory test, they currently have a hepatitis C infection. If the infection is still in the acute phase, there is a chance that it will be cleared by the body.

The provider will be contacted by the laboratory about the confirmatory test result and will be able to communicate the result to the person who had the test.

Dried blood spot testing

Dried blood spot (DBS) testing is another way to take a blood sample for testing in a laboratory.

- DBS testing uses blood from a finger prick that is collected as blots on a paper card and dried at room temperature.

- The card is then mailed to a public health laboratory for standard two-step hepatitis C testing.

A benefit of DBS testing is that multiple spots of blood can be collected on one card. This means that, like reflex testing, both screening and confirmatory testing can be done on the samples from one card. Another benefit of DBS testing is that it can help reach people in rural and remote regions. However, very few laboratories in Canada are currently able to process DBS testing cards.

Hepatitis C point-of-care (POC) testing

Hepatitis C point-of-care (POC) testing is a rapid test that allows hepatitis C antibody screening to happen at the location where blood is taken, using a couple drops of blood from a finger prick. The person being tested can get their result at the same appointment.

The only hepatitis C POC screening test currently approved in Canada is called the OraQuick® HCV Rapid Antibody Test. This test requires a couple drops of blood from a finger prick to test for hepatitis C antibodies. The test delivers results in 20 to 40 minutes.

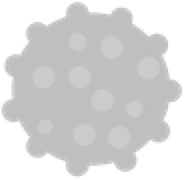
There are oral fluid-based hepatitis C POC screening tests in use in other countries, however, none of these tests are approved for use in Canada.

POC testing for hepatitis C antibodies is not widely available in Canada. Where it is used, it is generally only available in a limited number of specified locations such as harm reduction programs and community-based health and social service settings.

What is the window period?

No test can detect hepatitis C immediately after infection. The **window period** is the time between when a person has been exposed to hepatitis C and when a test can tell they have hepatitis C.

It is important to understand the concept of the window period to know when someone should test for hepatitis C in order to get the most accurate result. If a person gets tested shortly after a potential exposure to hepatitis C, it may be too early for the hepatitis C test to tell for sure whether they have hepatitis C.



What are the window periods for hepatitis C tests used in Canada?

The length of the hepatitis C screening test window period is determined by how long it takes for a person to develop hepatitis C antibodies.

- It usually takes about six to nine weeks for the body to make enough hepatitis C antibodies to be detectable by the test.
- A test result could be negative (non-reactive) despite the person actually having an acute hepatitis C infection, because their body has not yet produced enough antibodies for the test to detect them.

Since the confirmatory, or RNA, test looks for the genetic material of the virus in the blood and not the body's immune response to the virus (like an antibody test), the window period is shorter. HCV RNA can be detected about one to three weeks after exposure.

How does the window period impact hepatitis C testing?

Health and service providers need to know that there is a window of time in which a hepatitis C test may not be able to rule out a new infection. The window period is especially important to consider when the person getting tested has had a recent exposure to hepatitis C. When a screening test result is negative after a recent exposure to hepatitis C, the person should be encouraged to get tested again after the window period to confirm they do not have hepatitis C. People should also be encouraged to test regularly for hepatitis C if they have ongoing potential exposures.

If a person has ongoing risks for being exposed to hepatitis C, their past history of hepatitis C will inform how they are tested in the future:

- If they have **never had a known hepatitis C infection** (i.e., they have never been tested or they previously tested negative for hepatitis C antibodies), they should get screened for hepatitis C antibodies on a regular basis.
- If they have **spontaneously cleared or cured a previous infection with treatment**, they will have hepatitis C antibodies for life. This means they do not require a screening test and should instead get tested using a hepatitis C confirmatory test on a regular basis.

Understanding sensitivity and specificity

The accuracy of hepatitis C tests is explained using the concepts of **sensitivity** and **specificity**, which are measures of test accuracy. The higher the sensitivity and specificity, the more accurate the test.

Sensitivity is the chance that a positive test result will correctly identify a person with hepatitis C antibodies for an antibody test or with hepatitis C infection for a confirmatory test.

- Higher sensitivity means there is a lower chance of false negative results (testing negative when actually positive).

Specificity is the chance that a negative test result will correctly indicate that a person does not have hepatitis C antibodies for an antibody test or hepatitis C infection for a confirmatory test.

- Higher specificity means there is a lower chance of false positive results (testing positive when actually negative).

Accuracy of tests used in Canada

Standard testing with hepatitis C antibody and RNA tests in Canada have sensitivity and specificity above 99%.

This means that both false positive and false negative results are very rare, at less than 10 false positive or false negative test results per 1,000 tests. In other words, if 1,000 people with hepatitis C were tested, less than 10 would incorrectly test negative. If 1,000 people without hepatitis C were tested, less than 10 would incorrectly test positive.

Using HCV core antigen tests as a confirmatory test in Canada is much less common. These tests are less expensive than RNA tests, but they have a lower sensitivity at about 94%, so there is a higher chance of false negative results. This means that if 1,000 people with hepatitis C were tested, up to 60 people would incorrectly test negative. The specificity of core antigen tests is similar to that of hepatitis C antibody and RNA tests at between 98% and 100%.

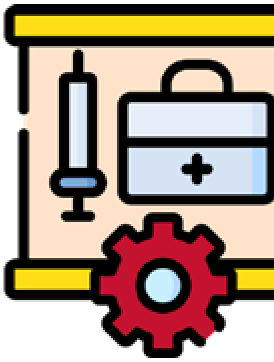
The POC test for hepatitis C antibodies, OraQuick®, has a very high specificity of 99% when used with finger-prick blood samples.

However, the OraQuick® test also has a lower sensitivity than antibody and RNA tests, at about 95.9% or higher. This means that if 1,000 people with hepatitis C were tested, up to 41 people would incorrectly test negative.

What happens after a hepatitis C-positive diagnosis?

After a person is diagnosed with a hepatitis C infection, several things should happen. First, newly diagnosed people need to be referred to care and treatment and any other supports they may need. Additionally, after a hepatitis C infection is confirmed, the positive result is reported to public health and efforts should be made to inform contacts who may have been exposed to hepatitis C.

Linkage to hepatitis C care, treatment and other services



Hepatitis C testing is an important entry point for people into services such as hepatitis C care, treatment and prevention, as well as other services such as harm reduction, social service supports and primary healthcare.

People who are diagnosed with hepatitis C infection should be provided with information about hepatitis C treatment and linked to care. Hepatitis C treatment is widely available and cures more than 95% of people with hepatitis C.

People who test negative but may continue to be at risk of acquiring hepatitis C should be offered information and resources about preventing hepatitis C infection and re-infection, including linkage to harm reduction services and repeat testing.

Public Health reporting and data collection

Positive hepatitis C antibody and confirmatory test results are reported to public health authorities because they are considered to be of significant importance to public health. They are reported to the provincial or territorial public health authorities where the person was tested.

When someone takes a hepatitis C test, some of their non-identifying personal information is collected. This may include their age, sex, city of residence, country of birth, ethnicity and their hepatitis-C-related risk factors.

Whether or not a person's name gets recorded depends on the testing option: nominal (name-based) or non-nominal (non-identifying) testing.

Nominal testing is available across Canada. The hepatitis C test is ordered using the person's name, the result is reported to public health using the person's name and the test result is recorded in their healthcare record.

Non-nominal testing is available in some parts of Canada. The hepatitis C test is ordered using the person's initials or a code or alias (depending on the province/territory), but not their full name. If the test is positive, the result is reported to public health using the person's name in most (but not all) provinces. The test result is also recorded in the healthcare record of the person being tested.

Anonymous testing is not available for hepatitis C in Canada.

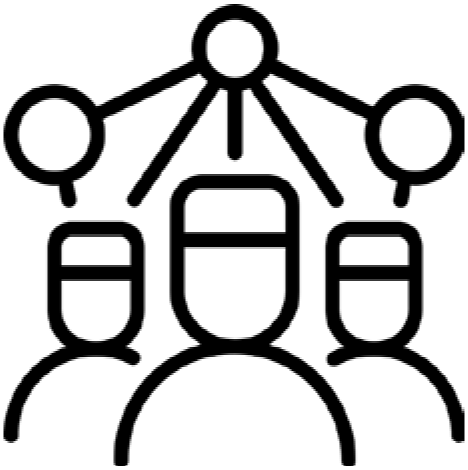
The amount and type of information collected and reported to public health depends on the province or territory where the test takes place. However, all provinces and territories provide non-identifying data on positive hepatitis C tests to the Public Health Agency of Canada for national-level reporting on hepatitis C in Canada.

Contact tracing and notification

Contact tracing and notification is the practice of identifying, locating and informing someone that they may have been exposed to hepatitis C. This is meant to encourage a person who may have been exposed to hepatitis C to get tested, in the hopes of identifying new hepatitis C infections as early as possible.

Public health in all provinces and territories carries out the function of contact tracing for infectious disease; however, this can look different depending on the province or territory.

When someone has a newly identified hepatitis C infection, a public health nurse or other healthcare provider may work with them to identify any contacts who may have been exposed to hepatitis C. Depending on local practices and capacity, the individual may be asked to inform their contacts themselves or a public health nurse or other healthcare provider may attempt to notify contacts and encourage them to test for hepatitis C.



UNIT FOUR

4 Key components of the HIV and hepatitis C testing process

At the end of this unit, you will be able to:

1. *Convey the importance of counselling, informed consent and confidentiality as part of the testing process.*
2. *Describe considerations for pre- and post-test counselling and for information provided to people before and after they test.*
3. *Explain the importance of linking people who get tested for HIV and/or hepatitis C to care and other health and social supports.*
4. *Describe how to link people to services/supports that can help them access treatment or stay HIV and hepatitis C negative.*

Introduction

With the push to scale up testing and diagnosis of HIV and hepatitis C both nationally and internationally to meet global targets, certain practices are needed to protect an individual's rights throughout the testing process.

The Public Health Agency of Canada's "HIV Screening and Testing Guide" recommends principles and core procedures for HIV testing across the country. This includes pre- and post-test counselling, informed consent and confidentiality. Guidance on these practices does not exist for hepatitis C; however, the same principles and standard procedures for counselling, informed consent and confidentiality are also applicable to hepatitis C.

This unit will explore these concepts and practices and will outline the role of service providers in supporting clients through the testing process by letting them know what to expect as well as the rights and information they are entitled to.

The 3 C's of testing

Respecting and protecting people's rights needs to be central to HIV and hepatitis C testing. In HIV testing guidelines, a human rights approach includes consideration of the "3Cs" of testing—counselling, consent and confidentiality. This also applies to hepatitis C.

Counselling involves having discussions with people throughout the testing process. It ensures that people receive the information, resources and supports they need both before and after taking a test.

Informed **consent** means that a person gives their approval to be tested with full knowledge of the possible benefits and risks of taking the test, which are explained during pre-test counselling. A person should not be forced to test and should be made aware of their right to decline testing, except for in very rare circumstances.

Confidentiality is an important consideration for a person who is deciding to be tested for HIV and/or hepatitis C. It is the responsibility of the person performing the test to ensure that test results and counselling discussions are kept confidential. However, since HIV and hepatitis C are public health issues, all positive test results in Canada must be reported to Public Health authorities.

Information and counselling

Any person who is tested for HIV or hepatitis C by a provider (not a self-test) should receive appropriate written or verbal information, as part of a counselling discussion, both before and after the test. The main purpose is to support people as they move through the testing process, regardless of their test result.

Pre-test counselling is important because it can help people make informed decisions about getting tested. Post-test counselling is also important because it can help people learn about steps they can take to support their health, including how to prevent passing HIV or hepatitis C if they test positive and how to prevent getting HIV or hepatitis C if they test negative.

Canada's "HIV Screening and Testing Guide" outlines recommended practice for pre- and post-test counselling. While no parallel national guideline exists for hepatitis C testing, counselling should be similar in order to ensure that the client is supported during the testing process. The main information that should be covered by pre- and post-test counselling for HIV and hepatitis C is outlined below.

Consent

Pre-test counselling includes a process for obtaining **informed consent**.

The pre-test counselling discussion provides information about the benefits and risks of testing to ensure that the person voluntarily agrees to test. This means that they can freely accept or decline a test without being pressured in any way.

HIV and hepatitis C testing do not require written consent. Verbal consent is sufficient, as it is with other medical tests.

If a person declines a test, the person performing the test should support the individual in a nonjudgmental discussion about their reason(s) for declining the test. This gives them the opportunity to correct any misinformation and to offer other information and/or supports or linkage to services.

When someone chooses to use a self-test for HIV, information provided through educational materials such as package inserts, videos and hotlines can help them make an informed decision about taking the test. Self-tests are currently not available for hepatitis C in Canada.

Pre-test counselling

The purpose of **pre-test counselling** is to provide information that can help a person make an informed decision about testing for HIV and/or hepatitis C and to prepare them for testing.

Pre-test counselling generally involves providing information or having a discussion about:

- a person's risk factors related to HIV and/or hepatitis C
- HIV and/or hepatitis C routes of transmission and prevention options (e.g., PrEP, PEP, harm reduction)
- information about advances in HIV and/or hepatitis C treatment
- the different options for testing (e.g., nominal, non-nominal or anonymous), if available
- the requirement to report positive test results to public health authorities
- what the test results mean
- next steps in the testing process, such as the need to return for test results in some cases
- window periods and follow-up testing timeframes
- possible need for comprehensive sexual health support and testing for other STBBIs (such as gonorrhea, chlamydia, syphilis)
- post-test support needs (e.g., professional counselling)
- referrals to healthcare and other services in the community (e.g., harm reduction services, PrEP for HIV, etc.)

Pre-test counselling should be tailored to reflect the diverse realities of people accessing HIV and hepatitis C testing. Because people who access testing have different experiences, exposures and testing histories, providers should tailor pre-test counselling to meet the context-specific needs of each individual.

For example, a provider may offer extensive pre-test counselling if a person has never been tested before, if they express concern about testing or if they have a high chance of getting a positive result. In other situations, a provider may choose to give written information to a person who gets tested regularly or whose preference is to receive written information.

In general, it is helpful to have plain-language written information on testing available for people getting tested. This can facilitate counselling discussions and make sure that all the necessary information is easily accessible.

Post-test counselling

After a person is tested for HIV and/or hepatitis C, the provider should offer post-test counselling or information whether they test positive or negative.

The post-test counselling process will vary based on the test result and the number of steps in the testing process (e.g., when a screening test is performed before and separately from a confirmatory test).

Post-test counselling for HIV

When a test reveals that the individual is HIV positive, the post-test counselling is extensive and will likely take place over time.

Post-test counselling after a positive result should include:

- explanation of the result, ensuring the person understands it
- enough time for the person to absorb the positive test result, discuss the impact of the result and ask questions
- discussion about advances in HIV treatment and care
- reassurance that people with HIV can live long, healthy lives
- comprehensive linkage to HIV care and treatment services
- information about HIV prevention (including how treatment and an undetectable viral load can prevent HIV transmission) and referrals to HIV prevention services (including harm reduction)
- referrals to professional counselling services, if required
- referrals to comprehensive sexual health support and testing for other STBBIs, if needed
- discussion about HIV stigma and disclosure (such as how, when and with whom someone might share their HIV status) and referrals to legal information about HIV disclosure
- discussion of the need for contact tracing and, if necessary, support to identify contacts for public health follow-up

When a test reveals that the individual is HIV negative, post-test counselling should include:

- explanation of the result, ensuring the person understands it
- discussion of any other questions about HIV testing, transmission or prevention
- counselling on when to test again if the person’s most recent exposure to HIV was within the window period (up to three months)
- recommendation to test regularly if there is an ongoing chance of getting HIV
- discussion about safer sex and/or harm reduction
- referral to relevant prevention services (e.g., PrEP or PEP, if appropriate)
- referrals to other community services as needed
- discussion of additional testing for sexually transmitted infections (STIs) or hepatitis C, if appropriate

Post-test counselling can occur at different visits depending on the type of HIV test.

For a standard test (a blood draw sent to a public health lab for analysis), the person is provided post-test counselling when the test result is ready (typically one to two weeks after the blood is drawn).

For an HIV point-of-care (POC) test, if the test result is non-reactive, the person is provided post-test counselling immediately after the result is available (in the same visit). With a reactive result, the person is given post-test counselling immediately after receiving the result and further counselling when they return to pick up the confirmatory test result (one to two weeks later).

Post-test counselling for hepatitis C

In general, when a hepatitis C test is reactive, the post-test counselling can be extensive, especially when a confirmatory test reveals that a person has hepatitis C and more time may be required to provide support and education.

Post-test counselling after a reactive/positive antibody test (either two-step standard testing or POC), **before confirmatory testing** should include:

- explaining the meaning of a reactive antibody test
- emphasizing the importance of getting a confirmatory test
- inquiring about potential previous hepatitis C infection
- referral to supports the person can access while waiting or to prepare for the possibility of a positive confirmatory test
- reassurance of the effective treatments that can cure most (95%) people with hepatitis C
- discussion of general hepatitis C prevention and harm reduction strategies, as appropriate
- referral to testing for HIV and other STIs if relevant

Post-test counselling after a positive confirmatory test (**meaning, the person has hepatitis C**) should include:

- explanation of the result, ensuring the person understands it
- enough time for the person to absorb the positive test result, discuss the impact of the result and ask questions
- reassurance that hepatitis C is a curable disease
- discussion of the effective hepatitis C treatments that have few side effects, last eight to 12 weeks and can cure most (95%) people
- discussion of treatment access, treatment readiness and a plan for medical follow-up, including assessment of liver damage

- discussion about the importance of early treatment initiation to mitigate long-term liver damage
- comprehensive linkage to hepatitis C care and treatment services
- review of harm reduction and general hepatitis C prevention so the person knows how to prevent passing hepatitis C to others and how to prevent getting re-infected after treatment
- discussion about maintaining liver health and other healthy living factors, including disclosure of hepatitis C status
- discussion of the need for contact tracing and, if necessary, support to identify contacts for public health follow-up

When a standard test or POC test reveals that the individual does **not** have hepatitis C, post-test counselling should include:

- explanation of the result, ensuring the person understands it
- discussion of any other questions about hepatitis C testing, transmission or prevention
- counselling on when to test again if the person's most recent exposure to hepatitis C was within the testing window period
- recommendation for repeat testing if there is an ongoing chance of getting hepatitis C
- discussion about the need for further harm reduction or safer-sex education or services
- referrals to other community services, as appropriate
- discussion of additional testing for STIs or HIV, if appropriate

Pre- and post-test counselling considerations

The counselling process and information that is provided should be adapted to each individual. It is important to tailor the amount and type of information and how it is presented to the person receiving the test.

For example, people who get tested regularly for HIV and/or hepatitis C may need less information, since they have already gone through the process several times.

Counselling should be tailored based on whether the person:

- seems overwhelmed by the information
- wants more information or less
- needs extra support to follow up on recommendations or referrals

Counselling should be done in a culturally safe way that respects the lived experience, cultural, sexual and gender diversities of people getting tested.

At each stage in the testing process, it is important to allow time for people to ask questions.

With regard to self-tests for HIV, package inserts, videos and hotlines can provide the necessary information to support people before and after taking the test. (Self-tests are not currently available for hepatitis C in Canada.)

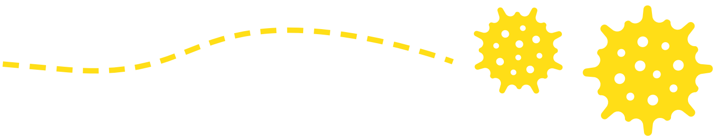
Confidentiality

The maintenance of **confidentiality** is an important consideration for a person who is deciding to be tested for HIV and/or hepatitis C. Stigma and discrimination are drivers of the HIV and hepatitis C epidemics and can act as a barrier to testing if people fear violence, social exclusion or legal consequences because of a positive diagnosis.

As with all medical information, it is the responsibility of the person performing the test to ensure that the confidentiality of the person being tested is maintained.

All interactions throughout the testing process are confidential, including a person's decision to get tested, their test results and anything they discuss with a testing provider during counselling. This means that although this information may be recorded in a person's medical file, it is kept private and not disclosed to anyone without the consent of the client. There are very limited circumstances in which confidentiality may be broken without consent. For example, the law may require personal information to be released in order to comply with a warrant or court order.

When HIV and hepatitis C testing is offered outside of a healthcare setting (such as in community-based organizations, bathhouses, shelters or mobile units), this can present unique challenges in maintaining privacy. Providers who offer testing in non-traditional settings should consider and develop procedures to make sure that confidentiality is maintained for people who test in these settings. This includes ensuring that interactions cannot be overheard by others.



People should be made aware of the fact that HIV and hepatitis C are both reportable diseases:

- HIV and hepatitis C are considered to be of significant importance to public health and all positive test results must be reported to public health authorities. The amount of personal information reported depends on the type of testing (e.g., nominal, non-nominal or anonymous), however, anonymous testing is available only for HIV and only at select sites in certain provinces.
- Contact tracing (when public health, the healthcare provider or the person being tested notifies their contacts about a potential exposure to HIV or hepatitis C) also has implications for confidentiality, even though the name of the person who tested positive is not disclosed.

Importance of linkage to care

HIV and hepatitis C testing is an important entry point for people into services such as HIV and/or hepatitis C care, treatment and prevention, as well as sexual health, harm reduction, housing, and mental health services.

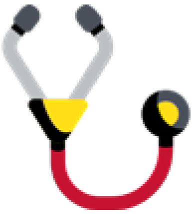
People who test negative but have an ongoing chance of getting HIV and/or hepatitis C should be linked to prevention services (such as PrEP for HIV or harm reduction services) and repeat testing.

People who are diagnosed with HIV and/or hepatitis C should be linked to, engaged in and retained in care and treatment. They should also be linked to information and services related to prevention in order to help them lower the chance of passing HIV or hepatitis C to other people.

Supporting linkage to care

Linkage to care should begin immediately after a diagnosis, however, sometimes it can take a while to get an appointment with a clinician. Some people need extra support to connect with a provider and remain engaged in HIV and/or hepatitis C care and treatment.

Providing immediate linkage to care can help people diagnosed with HIV and/or hepatitis C become engaged in care as soon as possible and can increase the likelihood that they will start treatment and successfully manage HIV or cure hepatitis C.



Service providers can support people to overcome the structural barriers that impede access to a healthcare provider after a diagnosis.

Some ways to support successful linkage to care include:

- immediate referral following a positive diagnosis, including the use of supported referrals (e.g., booking appointments for clients and accompanying them)
- use of strengths-based case management (where a case manager supports clients to access a clinician over a defined period of time)

- use of peer support, health navigators or case managers and other linkage support from people with shared culture and language
- intensive outreach to those who do not engage in care within one month of diagnosis

- providing transportation services or subsidies to support clinic attendance
- monitoring and evaluation of successful entry into care
- developing relationships with HIV and hepatitis C treatment providers and advocating on behalf of clients