Coronavirus disease (COVID-19)

Pan-Canadian COVID-19 Testing and Screening Guidance: Technical guidance and implementation plan

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Orientations pancanadiennes sur les tests et le dépistage pour la COVID-19 : Orientation technique et plan de mise en œuvre

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

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Background

The onset of the global COVID-19 pandemic in early 2020 triggered the need for coherent, pan-Canadian guidance on provincial and territorial testing. The federal, provincial and territorial Special Advisory Committee finalized and approved initial interim guidance on laboratory testing on April 16, 2020. The guidance focused on molecular polymerase chain reaction (PCR) as the sole laboratory test for accurately identifying SARS-CoV-2 in patients.

In May 2020, based on new evidence, the *National Laboratory Testing Indication Guidance for COVID-19* was updated to reflect developments in 4 areas:

1. expanded laboratory resources
2. viral transmission from asymptomatic individuals or those in the pre-symptomatic phase
3. outbreaks in congregate living and work settings
4. new testing modalities (molecular point-of-care and serological tests)

In October 2020, the guidance was updated to give a national perspective on testing and screening approaches. Recognizing that one size does not fit all, the guidance outlines approaches and tools that federal, provincial and territorial partners may adapt as the pandemic evolves.

Federal, provincial and territorial governments first endorsed this *Pan-Canadian Testing and Screening Guidance* in October 2020. This guidance outlines a portfolio approach that uses different testing technologies for diagnostic testing, screening and surveillance.

In addition, the Public Health Agency of Canada updated its Guidance on rapid antigen detection tests (RADTs) in February 2021 to include information on novel RADT technologies. The update included details on performance and potential use cases including:

- routine outbreak monitoring
- monitoring in high-risk settings (for example, long-term care facilities)
- possible adaptation into mobile rapid testing in rural and remote communities

In May 2021, Health Canada approved the first self-test for use in Canada. The Lucira “Check It” COVID-19 Test Kit is a nucleic acid self-test. As of July 28, 2021, Health Canada has authorized 77 COVID-19 testing devices (nucleic acid, antigen and serological). Authorized tests use various sample types, including saliva, nasal and nasopharyngeal. Thus far, there is no evidence of variants able to escape detection through existing testing technologies.

External expert advice has also helped to inform the approach to testing and screening. For instance, Canada’s COVID-19 Testing and Screening Expert Advisory Panel has published 5 reports to the Minister of Health on optimizing testing in Canada, long-term care, schools, borders and self-testing. The Industry Advisory Roundtable on COVID-19 Testing, Screening, Tracing and Data Management has published responses to the Expert Advisory Panel’s reports on optimizing testing at borders. It has also published reports on the importance of task-shifting and the self-administration of tests in workplaces.

Since the publication of the initial *Pan-Canadian Testing and Screening Guidance*, much of Canada has experienced a significant third wave. Rapid tests have been procured and made available to provinces and territories in large numbers. Workplace screening programs have been developed and deployed. Highly effective vaccines have also been authorized and administered to many Canadians.

With rising vaccination rates, the incidence and rate of transmission of COVID-19 has decreased (see eLife, ECDC technical report). Nevertheless, outbreaks continue to occur, with the vast majority among people who are not vaccinated, including those who may also face other health, social and economic barriers.

Some research indicates that vaccinated people who test positive for COVID-19 and do not carry the Delta variant are likely to have low viral loads (Teran and others, Bailly and others). There is also evidence that vaccination can greatly reduce rates of SARS-CoV-2 infections that have high viral shedding and symptoms.

Emerging evidence for the Delta variant points to the possibility of high viral loads in some breakthrough cases in fully vaccinated people, which can be as high as in unvaccinated people. Preliminary data from the U.S. Centers for Disease Control and Prevention and from Public Health England indicate that levels of virus in fully vaccinated people who become infected with Delta may be similar to levels found in unvaccinated people, and therefore they may be as likely to transmit the virus. These new studies highlight the importance of monitoring and responding to the ever-evolving science.

With vaccination rates contributing to decreases in the incidence and prevalence of COVID-19, as outlined in Testing for COVID-19 in vaccinated populations, it is appropriate to consider how testing, screening and surveillance strategies should be adjusted. Strategies should reflect the changing dynamics of the pandemic as both vaccination and variant of concern rates increase.

The main objective of this guidance is to support the effective deployment of testing, screening and surveillance as public health tools. Considerations are provided for developing and implementing testing, screening and surveillance approaches where a majority of Canadians are now fully vaccinated.

Recognizing that testing regimes are within provincial and territorial jurisdiction, this guidance reflects the changing landscape of testing and screening. It also highlights the innovation and collaboration that have taken place within and among jurisdictions.

Principles-based testing approach

As more and more Canadians are vaccinated, the demand for testing and screening is expected to decrease. This is because of the protection that vaccination offers against COVID-19, and also because vaccinated individuals with COVID-19 are less likely to be symptomatic. However, there will still be a need to manage new waves and/or localized outbreaks, including testing of symptomatic individuals and close contacts of individuals who have tested positive, regardless of vaccination status. Close contacts of individuals who have tested positive should be tested as outlined in the national guidance on case and contact management. Individuals are also encouraged to consult local public health guidance related to isolation and self-monitoring. Meeting surges in testing and screening demand will require a shift, with the appropriate testing technology used for the situation (for instance, local vaccination rates and epidemiology).

Testing and screening strategies for public health purposes in a vaccinated population should consider the following 4 key variables:

1. community prevalence of COVID-19
2. community prevalence of variants of concern (VoCs)
3. presence of outbreaks
4. populations with vulnerabilities

Another goal of these strategies is to ensure there is sufficient capacity in place to respond to increases in cases and potential outbreaks. This approach will help protect those most at risk.

Community prevalence of COVID-19

Community prevalence is the proportion of a population with COVID-19 at a given time. Definitions for what constitutes high or low community prevalence should be developed by jurisdictions based on their broader community context.

Along with test sensitivity and specificity, the pre-test probability of disease affects test performance. All other things being equal, when community prevalence of disease is lower, the pre-test probability is also lower. A positive result is more likely to be a false positive when prevalence is low. A negative result is more likely to be a false negative when prevalence is high. Testing and screening are more effective when prevalence is higher.

Surveillance data will be needed to monitor community prevalence and inform testing and screening decisions. Data from the following sources can be used to track prevalence:

- sentinel surveillance sites
- health records
- illness and severe outcome surveillance (for example, emergency room data)

Confirming point-of-care rapid test results that are presumed to be positive using lab-based PCR will provide important surveillance information. Genome sequencing follow-up for VoCs will also be possible.

Wastewater surveillance also provides information about COVID-19 in the community.

Community prevalence of variants of concern (VoCs)

A VoC is a mutated SARS-CoV-2 virus. The mutations affect one or more characteristic that is responsible for increased transmissibility, increased virulence or change in clinical disease progression. The mutated virus may also decrease the effectiveness of available diagnostic tools or vaccines.

New VoCs are likely to emerge while the virus continues to circulate globally. If VoCs emerge that evade vaccine-mediated immunity, the community incidence of COVID-19 will likely increase. As well, if vaccine-escape VoCs develop, the pre-test probability of vaccinated populations will also likely increase because vaccinated populations will be more likely to test positive for COVID-19. This will necessitate a larger role for testing and screening.

Testing and screening may also play a larger role in helping to protect populations with vulnerabilities where VoCs are more easily transmissible or may seriously compromise the health of those infected.

Presence of outbreaks

An outbreak occurs when there is uncontrolled transmission of the SARS-CoV-2 virus. In vulnerable or congregate settings, as few as 2 cases may be considered an outbreak.

In outbreak situations, testing and screening are critical to identify cases quickly in order to reduce transmission and prevent the infection from spreading further.

Populations with vulnerabilities

Testing and screening are also critical for populations with vulnerabilities. People who benefit most from a targeted testing strategy are those who are:

- clinically vulnerable to more severe outcomes
- vulnerable to infection

In some settings, such as long-term care and acute care facilities, tolerance for outbreaks is much lower because the risk of severe illness from COVID-19 is higher. There are also settings that are vulnerable because cases are difficult to manage due to limited access to health care services (for example, rural and remote areas). The risk of transmission is also higher in congregate settings, high-density living arrangements and workplaces where people are in close contact. People who are not vaccinated are also more vulnerable than those who are vaccinated.

Testing, screening and surveillance technologies

Moving into the second half of 2021, we can expect to rely more on existing and new testing technologies, including the following:

- multiplex assays to test simultaneously for COVID-19 and other respiratory infections (such as respiratory syncytial virus, or RSV, and influenza)
- testing and genome sequencing for SARS-CoV-2 and its VoCs
- self-tests and emerging novel testing technologies, such as COVID-19 breathalyzer tests

Increasing the accessibility of testing technology, particularly to populations with vulnerabilities, and supporting large-scale surveillance to monitor community spread will continue to be important.

When using tests with good sensitivity and high specificity, the proportion of false positive results is lower among those testing positive in higher prevalence settings. These include areas where there are outbreaks or where a large proportion of the population is not vaccinated. Screening programs using rapid tests in such circumstances have proven successful and cost-effective.

Positive results from tests with high specificity (99.9% specific) are more likely to be false positives in low prevalence settings, such as those where most or all are vaccinated.

When prevalence is very low, non-targeted asymptomatic rapid test screening may require many lab-based PCR tests to verify positive cases. The health, social and economic implications for those who receive false positive results are significant. The costs of false positives can be mitigated through confirmatory testing using a diagnostic test and provision of support strategies (for example, sick leave to offset loss of income).

Table 1: Characteristics of currently available testing technologies

Testing Technology	Nucleic acid detects viral genetic material most accurate	Antigen detects viral protein less accurate
Laboratory performed by a trained person	**PCR** • Most sensitive/specific and used for diagnostic purposes • Slowest: up to 1 to 2 days turnaround time • Can screen for known VoCs • 70% to 90% sensitive * and 95% to 99% specific* when symptomatic	**N/A**
Rapid Point-of-Care performed or supervised by a trained person	**PCR** • Equally or slightly less accurate than lab-based PCR • 15 min to 1 h turnaround time **LAMP** • Equally or slightly less accurate than lab-based PCR • 15 min to 1 h turnaround time	**Rapid Antigen Detection Test (RADT)** • Less accurate than lab-based PCR • Low accuracy in asymptomatic people with low viral loads • 15 to 30 min turnaround time

Testing Technology	Nucleic acid detects viral genetic material most accurate	Antigen detects viral protein less accurate
Self-test performed completely independently	**LAMP** • Less accurate than laboratory-based PCR • Decouples testing from public health reporting system • Up to 30 min turnaround time	**Rapid Antigen Detection Test (RADT)** • Least accurate vs lab-based PCR • Decouples testing from public health reporting system • 15 to 30 min turnaround time

* https://www.publichealthontario.ca/-/media/documents/lab/covid-19-lab-testing-faq.pdf?la=en
https://www.finddx.org/covid-19/sarscov2-eval-molecular/molecular-eval-results/
https://faseb.onlinelibrary.wiley.com/doi/10.1096/fj.202001700RR

Lab-based molecular tests

Typically, a laboratory-based PCR test is suitable to diagnose people with symptoms and close contacts of individuals who have tested positive, and to confirm the results of rapid tests. This test can also be used to screen for known variants of concern by using genome sequencing to analyze samples in depth. When capacity is limited, the principles-based approach can help decide which groups and settings are priorities for lab-based molecular testing. Sample pooling is another method for saving time and reagents when testing capacity is limited.

Point-of-care molecular tests

These tests may be suitable at a point-of-care setting because they are more sensitive and can detect infection when the patient has a low viral load. They are preferable to RADTs when definitive results are crucial, such as during an outbreak in a congregate setting. Point-of-care molecular tests can also be used in rural and remote communities.

Rapid antigen detection tests (RADTs)

One study found lower effectiveness of RADTs in breakthrough infections of vaccinated individuals. However, specific variants may result in higher viral loads, even in people who are vaccinated individuals. This would affect the performance of RADTs depending on the community context. The decision to use RADTs should be guided by the 4 key variables noted above, with the goal to protect populations with vulnerabilities, including in settings where a high proportion of people are not vaccinated or there are other risk factors. In these circumstances, it may be beneficial to test people who are vaccinated.

If the overall community vaccination rate is low, RADTs can also be used to identify paths of transmission. When used for screening, the regulatory guidance indicates RADTs should be used serially (for example, take the test twice over 2 or 3 days with at least 24 hours and no more than 36 hours between tests). Nevertheless, if community incidence is low and vaccination helps to reduce COVID-19 incidence, screening programs are less likely to be cost-effective (see testing in schools briefing, testing in business sectors briefing, Testing and Screening Expert Advisory Panel report, Ontario Science Table report). Confirmatory testing of positive results with more accurate tests may place burdens on public health systems, but would also provide a means of VoC screening/sequencing. It should be emphasized to those being screened with RADTs that a negative test result should not lead to a reduction in preventative measures.

Multiplex tests

Multiplex tests can detect the presence of genetic material from multiple viruses/infectious agents using a single sample. For example, they can determine if a person in hospital with symptoms of respiratory illness is infected with SARS-CoV-2, influenza, both or neither.

Their use at sentinel surveillance sites can provide insight into the prevalence of COVID-19 and other respiratory viruses, such as influenza and RSV.

Multiplex tests may also be used to:

- inform treatment for immunocompromised people or those with severe illness in acute care settings
- identify the virus responsible in people living in congregate settings who present with symptoms

As these tests are more costly, priority should be for those at highest risk of severe outcomes, where test results can guide treatment and care, and where the results can contribute to overall respiratory viral surveillance.

Wastewater surveillance

Wastewater surveillance can detect changes in COVID-19 at a community level. Wastewater is collected from treatment plants, pumping stations or other upstream community locations and the levels of SARS-CoV-2 and its VoCs are measured. PCR technology is used to test the samples. Wastewater samples can also be used for genome sequencing to detect existing and emerging VoCs in the population. Wastewater surveillance for COVID-19 is still emerging in its development and use, and challenges remain when it comes to detecting SARS-CoV-2 in wastewater.

Data for wastewater testing could complement COVID-19 surveillance systems by providing readily accessible pooled community samples and data for communities where testing is not available or underutilized. Thus, it can complement COVID-19 surveillance systems. Protocols for using point-of-care molecular tests to analyze wastewater are being developed.

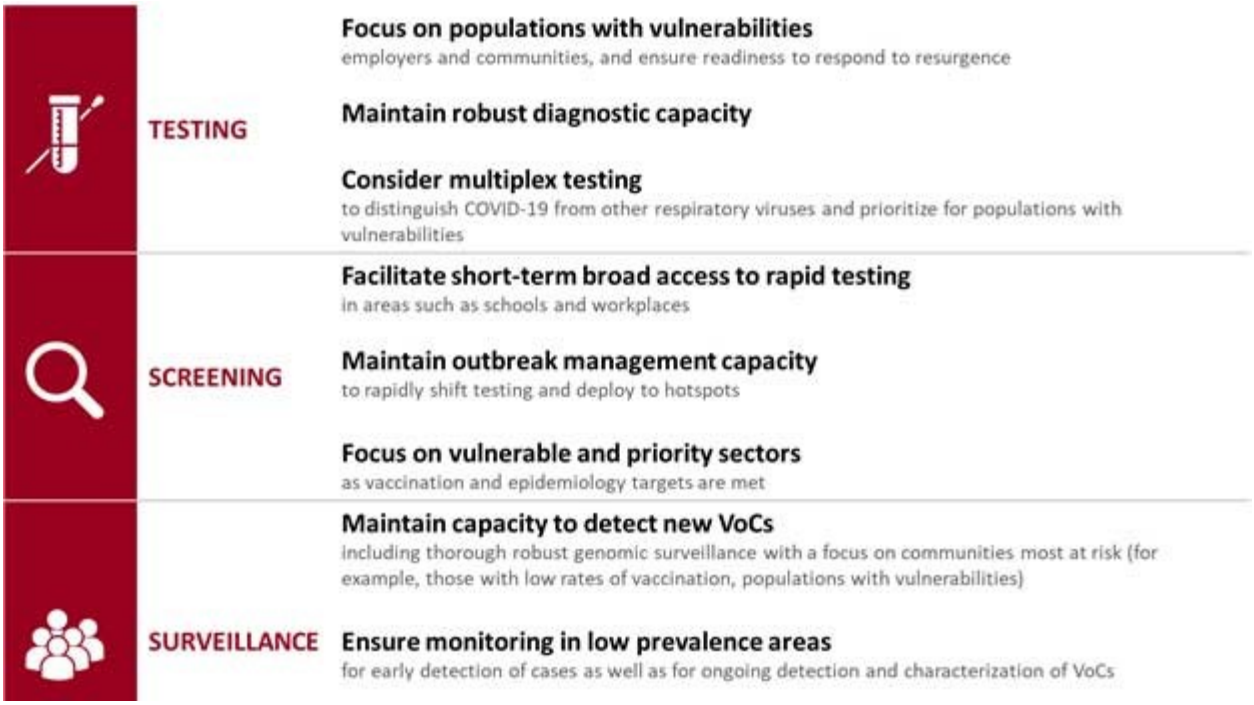
Testing, screening and surveillance framework

This framework is based on the evolving public health evidence, changing pandemic context and emerging technologies. The updated framework takes a broad approach that leverages and tailors technologies for testing, screening and surveillance while protecting and expanding the resilience of federal, provincial and territorial capacity. The intent is to target testing resources to the most relevant test in particular situations or use cases to address specific problems or purposes.

As the pandemic evolves, testing resources should support resurgence planning, outbreak management and re-opening while also:

- employing a right-sized and strategic approach focused on at-risk and vulnerable/congregate spaces
- ensuring flexibility to respond quickly and scale up efforts if needed
- being based, where applicable, on the program settings, scientific evidence and available and emerging testing technologies

Figure 1: Technology streams of a pan-Canadian framework for COVID-19 testing, screening and surveillance



Throughout the pandemic, significant diagnostic testing capacity has been established across Canada. Moving forward, it will be important to maintain a robust capacity and be able to ramp up quickly in hotspots and respond to outbreaks. As other respiratory viruses emerge alongside COVID-19, multiplex tests will be helpful to quickly distinguish COVID-19 from other respiratory diseases. A transition to more primary/ community-care settings for diagnostic testing will be important to focus on populations with vulnerabilities, employers and communities, and ensure readiness to respond to resurgence.

To date, rapid tests have been used to support widespread screening efforts to quickly identify cases in, for example, workplaces, community settings and schools. To support the shift from managing the pandemic to sustaining recovery and reopening, it will be important to:

- maintain the capacity to quickly deploy and scale screening capability
- focus our efforts on vulnerable and priority sectors
- support the rapid response to outbreaks

Partnerships with the private and not-for-profit sectors will be critical as well. Building on the lessons learned from workplace screening programs, these sectors can help us spread awareness about disease prevention and health promotion in the workplace. In addition, partnerships can be leveraged to facilitate data sharing and to fill data gaps on testing, screening and surveillance programs.

Monitoring low prevalence areas to detect COVID-19 cases early on as well as detect and characterize variants will also be critical. Efforts to enhance surveillance capacity (for example, by expanding wastewater and genomic surveillance) will be helpful in monitoring COVID-19 levels and VoCs in a community. Ongoing surveillance should also leverage established respiratory virus surveillance systems (for example, Fluwatch).

Five key foundational, interrelated pillars support the advancement of the framework:

- scientific integrity
- regulatory excellence
- procurement and deployment
- robust data and capacity
- strategic communication and partnerships

Continued updates to key guidance documents founded on rigorous scientific integrity will inform the evolution of testing approaches in Canada and support jurisdictions in the timely use of available technologies. Regulatory excellence will continue to be a focus, as it underpins the integrity of testing and screening strategies by assuring users that devices available in Canada meet stringent safety and efficacy standards. Procurement and deployment of tests will continue to focus on ensuring steady access to equipment and supplies for testing and screening wherever warranted. Furthering work in progress through the Pan-Canadian Health Data Strategy to ensure the availability of timely and comprehensive data will provide the evidence to underpin decision-making by governments.

Finally, in addition to strong federal, provincial and territorial partnerships, relationships with key partners in industry and the scientific community have been essential to the COVID-19 response. Ensuring rapid and effective progress is important, as is communicating what we know, what we are doing and what we are going to do. Strategic communications and partnerships are critical to informing people living in Canada of the continued importance and benefits of testing, screening and surveillance.

The continuous updating of this guidance will rely on strong federal, provincial and territorial partnerships and collaboration that leverage key governance bodies, including the Special Advisory Committee. The guidance will also capitalize on opportunities to leverage input and the capacity to mobilize knowledge in Canada and from around the world.

Looking forward

This guidance will evolve as the state of knowledge and risk management strategies continue to adapt to changing conditions. Guidance on current and emerging innovative testing and screening technologies will be adjusted to reflect new information concerning their performance in vaccinated context and how they meet the needs of various populations. As researchers and companies continue to innovate and develop new technologies and solutions, guidance will need to keep pace with, and take advantage of, these innovations.

Moving forward, testing and screening will continue to play a role in managing the pandemic. The epidemiology of the pandemic and the overall prevalence of COVID-19 will evolve based on factors such as the prevalence of COVID-19 and its VoCs, Canada's rates of vaccination and impacts of COVID-19 on populations with vulnerabilities. In vaccinated and unvaccinated populations, novel technologies including RADTs and self-tests will have ongoing uses for testing and screening, surveillance and outbreak responses.