

Position Paper January 2021

Call for Comprehensive COVID-19 Testing Strategies in Canada

Summary

We are currently in the second wave of the pandemic and the incidence of COVID-19 continues to increase, further exacerbating the drain on healthcare resources and the wellness of infected people. Testing for COVID-19 has been a key cornerstone of the public health strategy of "test, trace, isolate, support".

Since the start of the pandemic, the vital role of Canada's laboratory medicine/in vitro diagnostic community has been acknowledged and testing continues to help inform, manage and control the pandemic. Laboratory medicine has significantly increased the volume of diagnostic testing for COVID-19 (Lab-based PCR test) from zero at the start of the pandemic to more than 12.6 M tests performed across the country by mid December 2020.¹

The following call to action aims to provide clarity and information to help understand the different types of COVID-19 tests, and to support comprehensive testing strategies in Canada that exploit the use of "all the tools in our toolbox". Comprehensive and well executed testing are the critical first steps to successful "*Test, Trace, Isolate, Support*" strategies to help manage and control the COVID-19 pandemic.



Background

Although SARS-CoV-2 emerged in fall 2019, its accelerated spread in December 2019 enabled its detection. Its deadly potential was acknowledged January 30, 2020 when the World Health Organization (WHO) declared COVID-19 a public health emergency of international concern. Efforts began to dedicate resources to diagnose patients, including:

- in vitro diagnostics capital equipment (instruments),
- Supplies (e.g., swabs for sample collection, reagents to run tests and basic laboratory supplies),
- Trained staff to run and interpret the newly developed tests, and
- Process logistics from acquiring patient samples to reporting of results

Since March 2020, testing has been a key cornerstone of the public health strategy of "test, trace, isolate, support". The vital role of Canada's laboratory medicine/ in vitro diagnostic community has been acknowledged and significant accomplishments continue to help inform, manage and control the pandemic including:

- Building infrastructure for COVID-19 testing
- Unprecedented collaboration to quickly develop, validate, and accredit a wide range of COVID-19 tests
- Adding logistics, equipment, supplies and staff to help address several of the challenges identified above
- Significantly increasing the volume of diagnostic testing for COVID-19 (Lab-based or PCR tests) from zero at the start of the pandemic to more than 12.6 M tests by mid December 2020.²
- Providing interpreted test results that inform patient treatment and management plans, as well as supporting our economic recovery
- 1 https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html?stat=num&measure=tested#a2 accessed Dec 15, 2020
- 2 https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html?stat=num&measure=tested#a2 accessed Dec 15, 2020



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Table 1 Summary of types of testing

Test Type Category	What is Tested	Primary Purpose	Sampling Methods	Setting	Scalability*
Antigen	Viral proteins	 Presumptive diagnosis Screening 	 Nasal / nasopharyngeal swabs 	Point-of-care Central or hospital laboratory	+++
PCR or nucleic acid	Viral genetic material	DiagnosisScreening	 Nasal / nasopharyngeal swabs, Saliva sample 	Point-of-care Central or hospital laboratory	+ +++
Serological (antibody)	Antibodies to SARS-CoV-2 (COVID Virus)	• Epidemiology	• Blood sample	Point-of-care Central or hospital laboratory	-/+ +++

Note: Point-of-Care means the technology can be used in decentralized settings (i.e. doctors' offices, pharmacies, clinics, schools, workplace)

* Scalability refers to the capacity to adapt to changes in demand.

Introduction of a number of testing options to complement Lab-based PCR testing (e.g. Point of care nucleic acid, antigen and serology testing). See table 1 for a summary of testing platforms.

Although two vaccines have recently been approved and more are expected, the national vaccination program will continue until through to the end of 2021³, and we can expect several more difficult months ahead.

There are three objectives for COVID-19 testing: screening (i.e., identify the potential cases), diagnosing (i.e., confirm diagnosis) and monitoring/epidemiology (i.e., past infections and/or immunity). The testing options listed above (Table 1) have also recently been reviewed by CADTH.⁴ Despite having options, there are still limits on testing capacity. For example, Lab-based PCR testing is often restricted to only individuals who are symptomatic or exposed to a diagnosed individual and there are surge capacity ceilings.

Vigilance will continue to be needed through 2021 and possibly into 2022. There are opportunities to optimize the role testing can have to help manage and control the spread of COVID-19 through the pandemic.

The Opportunity

Modeling studies show outbreak control depends largely on the frequency of testing and the speed of reporting and is only marginally improved by high test sensitivity.^{5,6} Diagnostic testing turn-around time (from sample collection to result reporting to patient) is also related to testing capacity.

It is beneficial to apply lessons learned from other jurisdictions about what has been successful and what has not (as related to diagnostic testing programs). There are useful insights from the negative experiences in several jurisdictions through the first and/or second waves. (e.g., United States, United Kingdom, France, and Italy), as well as from jurisdictions that have successfully managed the first and/or second waves (e.g., Atlantic Canada, New Zealand, Australia, Israel, Greece, Taiwan, and Vietnam).

- 4 COVID-19 Testing: A summary of Testing Methods. Ottawa. CADTH, 2020 Dec. (CADTH horizon scan)
- 5 Interim Guidance for Antigen Testing for SARS-CoV-2
- 6 Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance).

³ Canada's COVIDCOVID-19 Immunization Plan: Saving Lives and Livelihoods, Dec 2020 Public Health Agency of Canada



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Diagnostic test suppliers may also be a helpful resource to share their perspectives on what works and what has not.

An important consideration in the development of more vigorous testing strategies to help manage COVID-19 infections is that community spread is often associated with individuals who are asymptomatic or pre-symptomatic⁷. Screening more widely and frequently could enable COVID-19 infected individuals to be more rapidly identified and isolated, helping to better manage and control the pandemic—supporting the opening of schools and institutions, and driving our economic recovery.

Expanded testing approaches would move us from being reactive (testing individuals who are symptomatic and have been exposed to a confirmed case) to being more proactive (including asymptomatic individuals) and would lead to more robust and comprehensive solutions to COVID-19 management and control.

Optimizing the toolbox of testing and tracing resources available will help manage and control the pandemic and support our economic recovery.

The Call to Action

We support the priority strategies identified by the COVID-19 Expert Panel.⁸ Canada needs comprehensive, robust, and effective testing strategies that use "all the tools in the toolbox" to manage and control the pandemic, as well as to drive our economic recovery. Enhancing our test, trace, and isolate approach will help to manage and control the COVID-19 pandemic more efficiently and effectively. This must include:

- Use of all testing approaches to identify cases in both symptomatic and asymptomatic populations
- Expanding contact tracing to locate potential areas of COVID-19 incidence (including non-traditional community settings), and
- Enhancing isolation and prevention strategies to help restrict disease spread.

These efforts are needed to manage and control the COVID-19 pandemic until the vaccination program is complete and takes effect.

About Medtech Canada

Medtech Canada is the national association representing the medical technology industry in Canada. Our association advocates for achieving patient access to leading edge, innovative technology solutions that provide valuable outcomes. Our members are committed to providing safe and innovative medical technologies that enhance the quality of patient care, improve patient access to health care, and help enable the sustainability of our health care system. The medical technology industry in Canada employs over 35,000 Canadians in approximately 1,500 facilities across the country.

The Canadian medical technology industry has been working around the clock to ramp up production, develop new innovative solutions and collaborate with our government and health system partners to fight the pandemic and help provide our healthcare heroes on the frontlines with the technologies and supplies they need to save lives. Whether it be diagnostic tests that enable the diagnosis of disease, personal protective equipment (PPE) for front-line health care workers or respiratory support equipment that aids in the healing of the sick, medtech companies in a variety of different product areas have taken significant actions to play a role in fighting COVID-19. For more info about the medical technology industry's response to COVID-19, please visit **medtechinnovation.ca**

- 7 https://www.who.int/news-room/commentaries/detail/transmission-of-sarscov-2-implications-for-infection-prevention-precautions
- 8 https://www.canada.ca/en/health-canada/services/drugs-health-products/ covid19-industry/medical-devices/testing-screening-advisory-panel/reportssummaries/priority-strategies.html



Appendices

Authorized medical devices for uses related to COVID-19: List of authorized testing devices

List of testing devices for COVID-19: applications under evaluation