Pan-Canadian COVID-19 Testing and Screening Guidance

Technical Guidance and Implementation Plan

Overview

As the global COVID-19 pandemic emerged in December 2019, the need for consistent, pan-Canadian guidance on provincial and territorial testing was quickly recognized. Led by the National Microbiology Laboratory, initial interim guidance on laboratory testing was developed in consultation with the Canadian Public Health Lab Network and was finalized and approved by the Special Advisory Committee on April 16, 2020. This guidance was based on scientific evidence and testing resources available at that time. The recommended screening guidance focused on the molecular polymerase chain reaction (PCR) as the sole laboratory technique to accurately identify SARS-CoV-2 in a patient sample.

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

- Expanded laboratory resources;
- Viral transmission from asymptomatic individuals or individuals in the pre-symptomatic phase;
- Outbreaks in congregate living and work settings; and
- New screening modalities (point-of-care molecular and serological tests).

The COVID-19 landscape has further evolved, and key aspects of this document must now be updated to reflect recent scientific and public health data. One key consideration relates to limiting asymptomatic diagnostic PCR testing where public health action would have significant benefits. Several pilot programs were launched in Canada, confirming very low levels of COVID-19 in the general population and supporting an evidence-based approach to the restart of economic activity. In addition, it enabled jurisdictions to stress-test screening capacity and prepare jurisdictions for higher screening volumes. Asymptomatic testing was also found to displace diagnostic capacity for symptomatic individuals, close contacts, high-risk settings and outbreak management. The *National Laboratory Testing Indication Guidance for COVID-19* document has been updated to reflect these findings and scientific advances.

Recognizing that screening plans fall under provincial and territorial jurisdiction, this document reflects the collaboration between jurisdictions, leveraging learnings from the various approaches adopted.

Emerging testing and screening technologies

The Pan-Canadian COVID-19 Testing and Screening Guidance is designed to reflect changing risk management approaches as the pandemic conditions change over time. Recognizing that one size does not fit all, the Guidance is also designed to respond to a significant increase in the need to access testing and screening technologies. Meeting increased and sustained testing and screening demand will require a paradigm shift by broadening the technologies that are used in a manner that is tailored to the purpose and application of technologies in a variety of settings. Although PCR remains the gold standard in diagnostic testing, numerous technologies and testing modalities are emerging that could serve to supplement diagnostic testing. These recent testing and sampling options could create opportunities to expand the testing approach by including broad-based approaches to screening through less sensitive tests and potentially more cost-effective technologies, thereby alleviating strain on the public health system as a whole.

While they can be less sensitive, these technologies could have multiple benefits, including ease and reduced cost of production, improved efficiency and reduced reliance on PCR testing supplies. They also have the potential to be less invasive depending on the technology. Antigen and extraction-free nucleic acid testing are examples of such technologies that, in addition to being more cost-effective and easier to produce, are also easily adaptable to mobile, rapid applications. However, due to their lower sensitivity than current PCR technology, these emerging technologies may be better used as part of screening, in conjunction with repeated testing in some settings. Recognizing that these novel technologies have lower sensitivity and specificity than current PCR technology, their use should be targeted to scenarios where both positive and negative are interpreted and acted upon appropriately.

Complementing the deployment of these emerging technologies, techniques such as pooled testing are being used to contribute to the preservation of testing resources. Governments are also tapping non-traditional data sources to complement case data. For example, 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.

As of September 29, Health Canada has authorized 36 COVID-19 testing devices (PCR and serological). Health Canada is fast-tracking the review of submissions related to antigen and nucleic acid tests. Submissions being reviewed include various sample types, including saliva. Consult the list of authorized medical devices for uses related to COVID-19 at https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html.

In anticipation of regulatory approval for antigen tests, an *Interim Guidance on Antigen Testing* has been developed to outline potential scenarios such as routine outbreak monitoring, monitoring in different situations including high-risk settings (for example,

long-term care facilities) and possible adaptation into mobile, rapid testing in rural and remote communities.

Pan-Canadian COVID-19 Testing and Screening Guidance

Like the Laboratory Testing Guidance, the Pan-Canadian COVID-19 Testing and Screening Guidance ("Guidance") is based on new public health evidence and emerging technologies, while adopting a broadened approach that leverages and tailors technologies to appropriate uses. The Guidance is designed to protect and expand the resilience of federal, provincial and territorial testing and screening capacity.

The Guidance is based on a portfolio approach that uses different types of testing technologies for various purposes (diagnostic, screening and surveillance). The intent of the Guidance is to better use testing resources to target the most relevant test in particular situations or use cases to address specific problems or purposes.

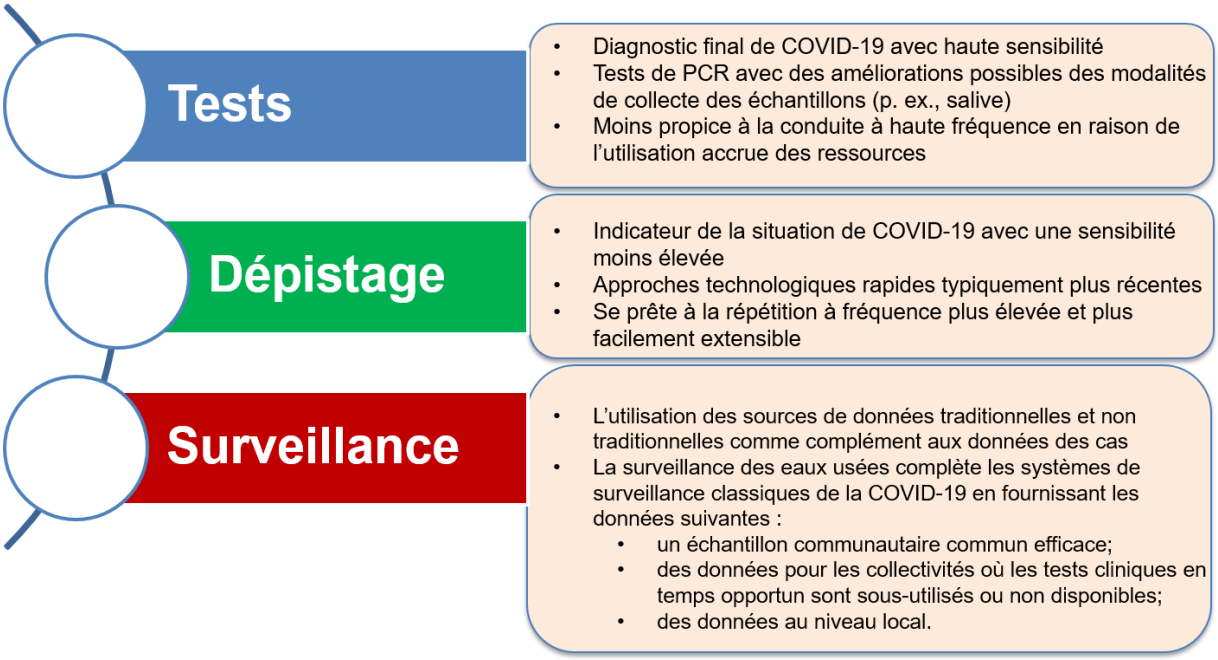

Figure 1: Technology streams of Pan-Canadian COVID-19 Testing and Screening Guidance

Five key foundational, interrelated pillars support the advancement of the Guidance: scientific integrity, regulatory excellence, proactive procurement, robust data and capacity, and strategic communication and partnerships.

Updates to laboratory testing and antigen testing guidance founded on rigorous scientific integrity enable and inform decision-making on testing allocations within Canada and support jurisdictions in the timely use of emerging technologies once regulatory approval is received. Regulatory excellence is equally important as a

foundational pillar to implementing the Guidance in a manner that allows for rapid approvals while still preserving the scientific integrity of the process.

In addition, undertaking a proactive procurement approach ensures steady access to equipment and supplies for testing and screening. Governments continue to take a proactive procurement approach, purchasing whenever possible, contingent on regulatory approvals.

Timely and comprehensive data is critical, underpinning decision-making by governments. Governments have established a new data set for COVID-19 cases that provides more targeted information, improving the ability to understand whether infections are acquired via domestic or international travel, or if they are linked to a known outbreak. Race and ethnicity indicators have been added as well as greater information on health care workers, allowing a better understanding of the COVID-19 experience among different population groups. In addition to the case data, key data on turnaround times for testing and contact tracing, for example, can also help identify issues related to capacity and timeliness of interventions.

Finally, in addition to strong federal, provincial and territorial partnerships, relationships are being further enhanced with key partners in industry and the scientific community. While ensuring rapid and effective progress is critical, it is also important to communicate what we know, what we are doing and what we are going to do. This collaboration and transparency supports critical decisions, including what additional capacity may be required as part of the Guidance, for instance, federal surge capacity to supplement provincial and territorial leadership. Strategic communications and partnerships are critical to maintaining and strengthening the confidence of Canadians in governments' actions to address COVID-19.

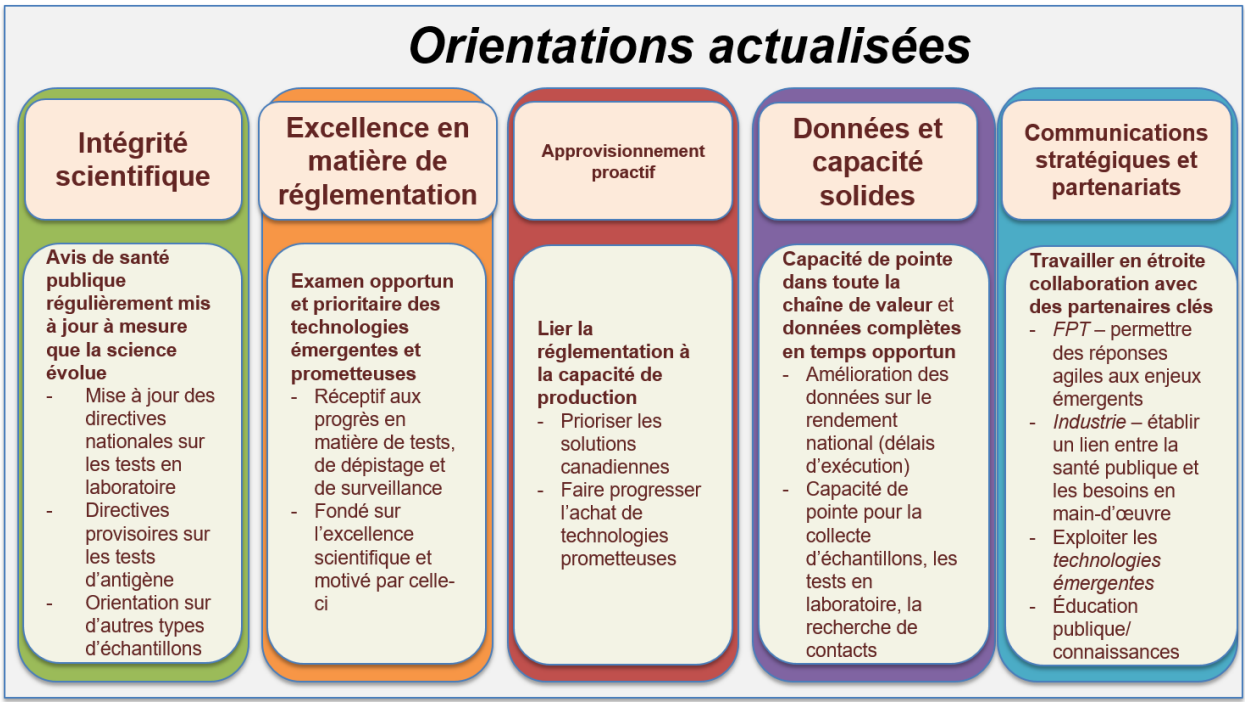

Figure 2: Implementation plan of the Pan-Canadian COVID-19 Testing and Screening Guidance

Looking forward

The Guidance is expected to evolve as the state of knowledge and risk management strategies continue to develop. Guidance on sample types is expected to be finalized during the fall, and the balance of testing and screening technologies will be adjusted to respond to the needs of various populations. 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. The continuous updating of this Guidance will rely on strong federal, provincial and territorial partnerships and collaboration leveraging 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 around the world.