

Information for the Standing Committee on Health: Laboratory Testing for COVID-19

PUBLIC HEALTH PERSPECTIVE

The Public Health Agency of Canada (PHAC) is pleased to provide this Committee with information about efforts PHAC is making to support laboratory testing for COVID-19 in Canada.

The mandate of PHAC is to promote and protect the health of Canadians. A significant component of PHAC's role is to prevent and control infectious diseases, and to prepare for and respond to public health emergencies. A key part of PHAC's COVID-19 response strategy is to ensure that sufficient public health capacity is in place to test, trace, and isolate cases of COVID-19. PHAC is supporting provinces and territories as they deploy testing to detect and control the spread of COVID-19. PHAC is taking all action necessary to protect the health and safety of Canadians during the COVID-19 pandemic.

PHAC works with Canada's public health leaders in provinces and territories to develop consistent laboratory testing guidance that is used according to specific regional contexts and circumstances. Emerging scientific knowledge is applied continuously in assessing testing guidance and adapting it according to the evidence. The Federal/Provincial/Territorial Special Advisory Committee on COVID-19 has recently completed an update of its testing guidance. Overall, the recommended approach to testing is to focus on symptomatic individuals (including those with mild symptoms) and prioritize those with symptoms for testing.

DEVELOPING A TEST

On January 7, 2020, PHAC's National Microbiology Laboratory (NML) convened a meeting with directors of the provincial public health laboratories across Canada to discuss preparedness and review guidance documents in light of the unfolding situation in Wuhan, China. The NML established a COVID-19 diagnostic test based on peer-reviewed published targets endorsed by the World Health Organization. On January 26, 2020, the NML received the first presumptive positive specimen, tested the specimen and confirmed Canada's first case of COVID-19 on January 27, 2020.

Once the first few cases were confirmed, laboratory extractions from the specimens were sent to provincial public health laboratories across Canada so that they too could offer testing in their labs with high confidence that the results were accurate. It was during these early days that the NML confirmed that all cases and presumptive positives underwent additional testing at NML. From there, provincial laboratories conducted extensive studies on how well their tests were performing, and they then started issuing confirmed cases directly, without needing further tests done at the NML.

CURRENT PUBLIC HEALTH PICTURE

As of May 14, 2020, 1,199,591 patients in Canada were tested for COVID-19. Total daily testing levels have approached 30,000 tests per day. As provinces and territories are putting in place re-

opening plans, all provinces and territories are planning to expand their testing capacity. Several provinces, such as Ontario and Quebec have publicly announced targets (e.g. Quebec to 14,000 tests/day, Ontario to 20,000 tests/day). At present, there is capacity in the public laboratory system in Canada to conduct up to 60,000 tests per day.

Laboratory-based **polymerase chain reaction (PCR) tests** are the only tests readily available that can detect an infection in the early stages, by collecting patient specimens by swabbing the upper part of the nasal passage. The sample is sent to a hospital or provincial public health lab, where specialized machines detect the virus's genetic material.

In addition to PCR testing, there are two other testing approaches that are currently under consideration, some of which have been adopted into the Government of Canada's overall testing strategy. This includes point-of-care testing and serological testing.

Point-of-care testing is an approach that can provide individuals with test results quickly (30 to 60 minutes). While more mobile than existing lab-based tests, this test platform is currently less efficient than laboratory-based tests as a limited number of tests can be completed in a day. This test platform is a complement to lab-based testing in this strategy, with particular value in remote/rural settings.

At present, one point-of-care test platform (GeneXpert) is approved for use in Canada. A Canadian company, Spartan, has a point-of-care test platform that is currently available for research use only.

As testing is expanded to support the re-opening of social and economic life, test limitations will be considered. Avoiding high rates of false-negative results is critical to reducing viral spread. Similarly high rates of false-positive results will result in limited resources being applied to unnecessary contact tracing.

Serological testing and serological surveillance for antibodies and potential immunity are critical in moving towards re-opening of society. Serology testing involves the testing of blood / serum / plasma samples to detect antibodies generated to the virus as part of the patient's immune response to the pathogen. The role of serology in the diagnosis of acute illness or patient management is limited due to the time taken for detectable antibodies to be produced after the onset of symptoms (several days to weeks depending upon the type of antibody).

Serology testing is used to indicate if an individual has been infected by the virus that causes COVID-19. The results of the test will play a key role in a number of public health investigations that seek to determine the immune status of those who have been infected. These tests will provide a means to understand community transmission and exposure rates of COVID-19, including to inform the development of COVID-19 vaccines. These findings can help policymakers and experts gauge how vulnerable a community remains to the virus and how frequently asymptomatic or mild cases occur.

It is important to note that serologic testing has not been validated as a routine diagnostic approach, and that molecular (PCR) testing approaches will continue to be the diagnostic standard.

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On April 23, 2020, Canada's COVID-19 Immunity Task Force was launched. Under this initiative, sero-surveys will be conducted to determine how widespread exposure to SARS-CoV-2 is in the population and in particular subgroups at high risk of exposure. Since persons who are asymptomatic or have mild cases of COVID-19 would unlikely seek medical attention where testing would be done, these studies are essential to our understanding of where exposure has occurred and the potential immunity of groups in the population. Integral to their interpretation is the immunological research underway to determine whether an immune response to SARS-CoV-2 confers immunity and the duration of this protection. The COVID-19 Immunity Task Force will coordinate with the provinces through the Conference of Deputy Ministers of Health, and link with other initiatives, such as work through the Canadian Institutes of Health Research.

PUBLIC HEALTH AGENCY OF CANADA INITIATIVES

Below are some initiatives led by PHAC which address challenges faced from a testing perspective.

Securing supply of reagents

PHAC has worked with federal partners to set up bulk procurement contracts with six major vendors who normally supply reagent to ensure security of supply in Canada. PHAC has also obtained a proprietary recipe from another reagent production company and is working with National Research Council to produce this reagent for additional supply. PHAC has also engaged LuminUltra Technologies to produce reagent for 500,000 extractions a week for the next 50 weeks. This meets current demand for extraction reagents in Canada. PHAC has also reached out to provinces and territories to organize a second round of bulk procurement contracts to ensure that the testing needs of provincial public health laboratories will be met going forward.

Securing supply of testing swabs

PHAC has worked with federal partners to procure swabs to support laboratory testing in Canada. This includes contracts for 12 million swabs between now and October 2020. PHAC is also engaged with other federal departments in exploring the domestic production of swabs in Canada. The procurement of swabs and domestic production options underway are expected to ensure provincial public health laboratories have sufficient supply of swabs for a sustained period of time to conduct COVID-19 testing.

Point-of-care test platforms and test kits

PHAC is actively engaged in working with provinces and territories to explore all options to build domestic capacity for point-of-care testing capacity. This includes supporting Spartan Biosciences in their ongoing development of the COVID-19 test. PHAC has also been working closely with provinces and territories to deploy the GeneXpert platform to remote hospitals

across Canada, improving access to testing for rural and remote communities. Moreover, PHAC has also offered training on operating the point-of-care test platforms to support testing in rural and remote communities.

Looking ahead, letters of intent have been issued with a number of companies that have a high potential to get to market quickly to ensure that Canada will be able to procure the point-of-care test platforms and kits as they become available.

Serological Testing

The Public Health Agency of Canada's National Microbiology Laboratory and its partners are working on developing a number of serologic tests in addition to evaluating a variety of commercial serologic tests for COVID-19. This pan-Canadian collaboration includes members of the Canadian Public Health Laboratory Network, clinical researchers from front-line health care settings, and Canadian Blood Services, all of whom are working to establish the materials needed for both the evaluation and then implementation of serologic testing.

CONCLUSION

Looking ahead, a rigorous testing approach is required to enable Canada to de-escalate certain public health measures. We will need a multi-pronged testing approach, encompassing PCR, point of care, and serology testing. This multi-pronged approach would have a focus on key populations, such as long-term care residents and health care workers, have granularity into case and contact tracing to ensure that individuals are traced, tested, and remain in quarantine, and testing information can inform modelling of the epidemiology curve to inform further de-escalation efforts.

As new testing products or platforms become available, PHAC continues to work with provincial and territorial partners to ensure there is adequate testing capacity and secure supply of tests to enable a return of economic activity in Canada.