There is a lot of discussion around the need for a significant in increase of access to testing. What can PHAC tell us about the current and future capacity for testing?

From Key Messages

Testing incidents under investigation

- Our top priority is the health and safety of Canadians.
- The Public Health Agency of Canada's National Microbiology Lab (NML) in Winnipeg is performing diagnostic testing for the virus that causes COVID-19.
- The NML is working in close collaboration with provincial and territorial public health laboratories to ensure that persons under investigation for the novel coronavirus are confirmed or ruled out through laboratory testing.
- Multiple provincial public health laboratories can now test for the novel coronavirus with a very high degree of accuracy.
- BC, AB, SK, ON, QC are able to confirm laboratory diagnostics for the virus that causes COVID-19. For all other provinces, their results undergo additional testing at NML because this is a previously unknown virus and it is good practice to use additional tests to provide further confirmation of initial laboratory findings.
- Presumptive positive cases that are identified through provincial/territorial testing are managed from a public health and infection control perspective in the same manner as confirmed cases.
- The Public Health Agency of Canada is in close contact with provincial and territorial counterparts.
- We will keep Canadians informed as the situation evolves.

Interim Order Respecting COVID-19-related Medical Devices

- Our top priority is the health and safety of Canadians.
- Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.
- As an emergency public health measure, the Minister of Health has signed an Interim Order to allow expedited access to COVID-19-related medical devices.
- With the Interim Order, two new diagnostic tests are made readily accessible in Canada:
 - the Roche Molecular Systems Inc. cobas SARS-CoV-2 diagnostic device; and
 - o the ThermoFisher Scientific TaqPath™ COVID-19 Combo Kit
- An Interim Order is one of the fastest mechanisms available to the Government of Canada to help make health products available to help address larger-scale, public health emergency situations.

From Evergreen QAs

Q1. How will these new test kits help test more patients?

This Interim Order makes it easier and faster for certain medical devices, such as laboratory diagnostic test kits, to be imported and sold in Canada. This would help improve access to medical devices that could permit faster and more convenient testing of patients, which would avoid needing to send samples to the NML lab in Winnipeg, facilitating quicker test results.

Point-of-care diagnostic tests are in development and may become available through this Interim Order, which would permit quicker and more convenient testing of patients. Quicker test results would enable healthcare providers and patients to take appropriate actions more quickly in order to help reduce the spread of the disease.

Criteria used to offer testing (priority groups) and whether uniform across country?

From Key Messages

Testing individuals

- Testing for the novel coronavirus in symptomatic individuals has clear clinical and public health value, but the same is not true for testing asymptomatic persons.
- Canada has and will continue to test all symptomatic individuals, as part of our evidencebased approach, while considering the evolving science on other testing scenarios. As the science evolves, our approach will keep pace, and policies and protocols will be updated accordingly.
- The value of testing asymptomatic individuals is unclear. Canada has and will continue to take a measured, evidence-based approach to all of these critical decision points around some of the key unknowns on COVID-19.
- One thing that is clear in our approach is that we test all symptomatic individuals and our threshold for that has been very low.
- It is important to understand that this is not a simple or straightforward issue, and the science is not clear.
- Testing asymptomatic individuals offers a false sense of reassurance, because it does not mean that an individual will not go on to become symptomatic and develop disease within the incubation period. The timing of testing matters. This is why we took the precaution to quarantine individuals again in Canada. There is a <u>real</u> assurance in monitoring for the 14-day incubation period and that means more for preventing spread than a potentially false negative test result.
- In addition, if an asymptomatic individual was tested and the test was positive, it is not clear what the significance and implications are. A positive test could mean presence of virus genetic material was detected, but that does not mean the person is necessarily infectious to others.

Why asymptomatic people are not being tested for COVID-19:

- It is important to focus on testing the right people at the right time.
- Testing in Canada is focused on people who present with symptoms consistent with COVID-19.
- Testing people who are asymptomatic is not considered an effective approach to detecting and preventing the spread of this virus and may give a false sense of reassurance.
- Most individuals tested to date have had symptoms and a history of travel, or contact with a traveller, to a known affected country.

- More recently, all travellers returning from any destination outside of Canada are being advised to monitor their symptoms. If they experience symptoms, they are asked to isolate themselves and contact their public health authority or health care provider who will determine whether they need further health assessment and testing.
- In addition, we are expanding testing for people without travel history by including testing of COVID-19 for patients who are already being tested for other respiratory viruses.
- This approach will help bolster our response by helping us quickly detect and monitor any potential community spread of COVID-19.

What is being done while point of care technology is not available yet?

From Key Messages

Expediting access to hand sanitizers, hard surface disinfectants, personal protective equipment and swabs

- Health Canada's top priority is the health and safety of Canadians.
- In light of the unprecedented demand and urgent need for products that can help limit the spread of COVID-19, Health Canada is facilitating access to products that may not fully meet current regulatory requirements, as an interim measure.
- This includes hand sanitizers, hard-surface disinfectants and personal protective equipment (such as masks and gowns), as well as swabs.
- For example, Health Canada will allow certain products of these types to be sold in Canada without being fully compliant to regulatory requirements, including:
 - products that are already authorized for sale in Canada but are not fully compliant with Health Canada's bilingual labelling requirements (e.g., labelling in only one official language, different packaging from what was authorized); and
 - products that are not authorized for sale in Canada, but are authorized or registered in other jurisdictions with similar regulatory frameworks and quality assurances.
- Health Canada is also expediting approvals of products, as well as establishment and site licences related to these types of products.
- Health Canada is working with Public Services and Procurement Canada, and Innovation, Science and Economic Development to identify manufacturers and facilitate rapid access to these necessary products.
- Health Canada is strongly committed to ensuring the safety of products, including products brought to Canada through these measures.
- The Department will continue to update Canadians on any further efforts to increase supplies of health products that may be used to help combat the COVID-19 pandemic.