Media Lines

COVID-19 Antigen, Rapid Point-of-Care, Saliva and At-Home Test Kits, Including Abbott

Issue: Health Canada continues to receive many media enquiries about saliva and other point-of-care tests for COVID-19.

On September 29, Health Canada published guidance on Canada.ca for industry on sensitivity requirements for COVID-19 antigen tests.

On September 29, the Government of Canada announced the purchase of 2.5 million Abbott ID NOW point-of-care test kits.

Key messages

- The Government of Canada understands the importance of increasing COVID-19 testing capacity as early diagnosis is crucial for slowing and limiting the spread of COVID-19 in Canada. That is why Health Canada has prioritized the review of all types of COVID-19 tests, particularly emerging and innovative testing options and technologies.

- As a regulatory body, Health Canada is doing everything in its power to give Canadians and the health care system access to as many testing options as possible in a timely manner, without compromising on safety.

- At Health Canada, we are closely monitoring emerging technologies. When we catch wind of promising new tests not yet available in Canada, we proactively contact the manufacturers to encourage them to enter the Canadian market.

- The Government of Canada is investing $4.28 billion to help provinces and territories cover the cost of increasing their capacity to conduct testing, perform contact tracing and share public health data that will help fight the pandemic. The goal is to ensure provinces and territories have the capacity to test around 200,000 people per day, nationwide.

- The Government's top priority is the health and safety of Canadians. Before a test is authorized for use in Canada, it must undergo a thorough review through Health Canada's regulatory process to ensure it is supported by sufficient evidence of safety, effectiveness and quality.

- Canada's regulatory system for medical devices, instruments and equipment is among the most rigorous in the world. Before authorizing a medical device, Health Canada takes steps to ensure that it meets appropriate safety, effectiveness and quality requirements.

- Health Canada is currently reviewing submissions for rapid point-of-care tests and will be prioritizing emerging and innovative testing options, including other rapid tests and at-home test kits.

- Health Canada is working quickly to approve rapid and point-of-care testing options based on molecular technology and antigen detection to fulfill Canada's testing needs without compromising the safety of Canadians.

- The Government of Canada is working proactively with companies in Canada and abroad that are developing emerging and innovative testing technologies.

- More information on testing is available here.

If asked about Abbott tests

- Abbott's toaster-size ID NOW COVID-19 test kit can give results within 13 minutes. The test can be administered in a variety of locations, including clinics and nursing stations.

- Scientists at the National Microbiology Laboratory (NML) are working closely with federal, provincial and territorial partners to maximize the availability of testing equipment at points of care and develop the best possible national distribution strategy for Canadians.

- Once the devices receive approval from Health Canada, the NML will work with provincial and territorial partners to review device performance and provide best practices for usage.

- The NML is offering ongoing support and technical guidance to people using these devices. This support includes a thorough quality assurance program to ensure that the devices continue to give reliable results.

If asked about other tests

- On September 23, 2020, Health Canada authorized Hyris Global test kits for point-of-care use.

- These point-of-care tests may be administered by qualified health professionals only.

- To date, Health Canada has authorized 36 COVID-19 testing devices for sale in Canada. A complete list of testing devices authorized by Health Canada is available at https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html.

If asked about point-of-care tests

- The Public Health Agency of Canada's National Microbiology Laboratory (NML) is working with provincial and territorial public health labs to ensure that COVID-19 tests give accurate results.

- Point-of-care devices allow tests to be administered in a variety of health care settings. They eliminate the need to send samples to a laboratory for analysis, meaning patients get their test results back sooner.

- Faster test results will allow patients who test positive, and their health care providers, to quickly take the necessary steps to limit the spread of the virus, such as treatment, contact tracing and self-isolation.

- Point-of-care testing is crucial in northern, isolated and remote communities, as well as in specific sensitive situations where it is important to get back test results quickly without having to send samples to a lab.

- Implementing point-of-care testing in communities, especially those in remote and northern regions, will help address testing gaps in underserved communities where it is difficult to get a lab test.

- Health Canada authorizes point-of-care testing after carrying out evidence-based scientific reviews guaranteeing test accuracy and reliability. The NML and its provincial partners contribute regularly by reviewing tests and sharing the results with Health Canada.

- A complete list of all COVID-19 testing devices and instruments is available on the Health Canada website at https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html.

If asked about antigen tests

- Antigen tests are used to diagnose COVID-19. They detect specific proteins on the surface of the virus.

- On September 29, 2020, Health Canada released information for industry on the minimum sensitivity requirements that their COVID-19 antigen tests must meet to be submitted for authorization. Sensitivity is a measure of test accuracy.

- Health Canada is advising industry that for their antigen tests to receive approval, companies must provide clear evidence that the tests meet the minimum requirement of 80% sensitivity to ensure they give reliable results.

- Health Canada welcomes emerging technologies and will prioritize submissions for all types of test kits. Only tests with proven accuracy and reliability will be authorized.

If asked about the mouth rinse and gargle lab tests administered in British Columbia

- Provincial health authorities have developed a new technique for sample collection that uses a mouth rinse and gargle method. This method will be used in British Columbia as an alternative to nasal swabs, especially for collecting samples from children.

- This technique involves swishing a saline solution and spitting it into a container for sample collection.

- Mouth rinse and gargle tests are considered lab-developed tests and are not subject to monitoring by Health Canada under the *Food and Drugs Act*.

  The collection device itself (i.e., the funnel in which the spit sample is collected) is a Class I medical device that may be imported or sold by holders of a Medical Device Establishment License issued by Health Canada.

- Health Canada and the Public Health Agency of Canada welcome all emerging technologies that will help combat COVID-19 and reduce its impact on Canadians.

If asked about encouraging authorization of new devices in Canada

- Health Canada is actively encouraging manufacturers in Canada and abroad to develop emerging and innovative testing technologies.

- Health Canada is advising companies on the regulatory process and assisting them with their device approval submissions. This support ensures that companies provide the information that Health Canada needs to quickly grant authorization and ramp up Canadian access to the tools needed to combat COVID-19.

- Health Canada also regularly contacts manufacturers who have obtained authorization from another jurisdiction to encourage them to make a submission to Health Canada.

If asked about information sharing on new device authorizations

- Health Canada is constantly updating its website with new information. For example, the Department recently added updated information on at-home tests and announced that submissions are open for all testing solutions.

Additional messages

- Health Canada is committed to equipping Canadians with the tools they need to combat the spread of COVID-19 in Canada.

- Early diagnosis is crucial for slowing and limiting the spread of COVID-19 in Canada.

- As a regulatory body, Health Canada is doing everything in its power to give Canadians and the health care system access to as many testing options as possible in a timely manner, without compromising on safety.

- To date, Health Canada has authorized 36 COVID-19 testing devices for sale in Canada. A complete list of testing devices authorized by Health Canada is available at https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html.

- Health Canada's consistent approach throughout the pandemic has ensured that the testing devices on the Canadian market are accurate and reliable. Canada has avoided some of the challenges that other countries have experienced with tests of poor quality.

- Health Canada is committed to ensuring that tests are safe and effective, while working to authorize testing technologies as quickly as possible.

- The Minister of Health has approved an Interim Order to expedite access to COVID-19 tests without compromising on device quality, safety and effectiveness (Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19).

If asked about saliva tests

- As of September 14, 2020, Health Canada had received two submissions for saliva tests (using spit), but had not received any submissions for mouth rinse and gargle tests, which involve swishing a saline solution.

- These submissions were prioritized and are currently under review.

If pressed on the authorization of Spartan test kits

- Health Canada is continuing to work with Spartan Bioscience Inc. in its efforts to demonstrate that its product works properly.

- Health Canada has provided Spartan Bioscience Inc. with regulatory guidance on conducting clinical trials for its testing device. Spartan Bioscience Inc.'s submission for authorization will be prioritized once it is received.

If asked about the approval of at-home sample collection by the U.S. Food and Drug Administration

- Health Canada has not yet received any submissions for at-home test kits or kits that involve collecting samples at home and mailing them in for analysis.

- Health Canada is aware that the U.S. Food and Drug Administration (FDA) has approved the COVID-19 RT-PCR test, which involves taking a liquid sample at home.

- Samples are taken at home using a nasal swab and are sent to a lab for analysis. They are subject to strict transportation requirements.

- Canada and the United States have different approval regulations and procedures. Each regulatory body reviews submissions based on its own requirements and criteria, which reflect the needs of its health care system.

- Health Canada's consistent approach throughout the pandemic has ensured that the testing devices on the Canadian market are accurate and reliable. Canada has avoided some of the challenges that other countries have experienced with tests of poor quality.

- Other international regulatory bodies, including the U.S. FDA, have not approved fully at-home COVID-19 test kits.

- Health Canada is open to reviewing all innovative testing methods as they become available.

If asked about the June 2020 Health Canada notice on out-of-lab and point-of-care testing

- In June 2020, Health Canada released guidance for industry to clarify its position on point-of-care and out-of-lab testing. At the time, the Department's position had to do with the use of at-home tests for diagnostic purposes. In response to the evolution of the pandemic, Health Canada may now review submissions for self-sampling or at-home testing kits intended for people with or without symptoms who wish to check and monitor their own infection status.

- Health Canada is open to reviewing all innovative testing methods as they become available.

Clarifications on the role of the National Microbiology Laboratory (NML)

- The NML provides critical scientific leadership for Canada's fight against COVID-19. It coordinates with provincial and territorial jurisdictions and labs, as well as Indigenous Services Canada, to distribute point-of-care testing instruments, devices and supplies to rural and isolated communities.

- The scientists at the NML are working to find the best way to increase device capacity using innovative testing methods such as sample pooling.

- As of September 30, the NML had held 40 distance and in-person training sessions for health professionals who would be using point-of-care testing devices.

- These training sessions allow professionals who will be using the devices to gain hands-on experience.

- The NML is offering ongoing support and technical guidance to people using these devices. This support includes a thorough quality assurance program to ensure that the devices consistently give reliable results.

- The NML has undertaken scientific studies on point-of-care tests and testing supplies to help provincial laboratories decide whether to adopt these tests for use in clinical settings. These studies are being conducted in partnership with provincial labs and clinicians to assess the accuracy of the tests under real-life clinical conditions. The results are being shared with Health Canada and are being taken into account in Health Canada's scientific review of submissions for authorization under the Interim Order to speed up access to COVID-19 medical devices.

- Findings on test accuracy are shared with the manufacturers, with all provincial laboratories and with Health Canada to increase the supporting evidence.

- The NML's priorities remain obtaining reagents for tests, reviewing rapid point-of-care tests and facilitating access to authorized test kits so that provinces and territories can ramp up testing as needed.

What are point-of-care tests?

- Point-of-care tests are performed at the time and place the patient receives care, such as a hospital or doctor's office. Point-of-care tests give results without requiring that samples be sent to another laboratory.

- The molecular point-of-care tests used to detect active cases of COVID-19 are similar to the Polymerase Chain Reaction (PCR) tests used in regular labs in that samples are swabbed from the nose or throat.

- The samples are then analyzed on site using automatic instruments that detect DNA sequences, such as GeneXpert or ID NOW by Abbott. Results are returned in 30 to 60 minutes for GeneXpert and 13 minutes for ID NOW. Lab professionals are not required.

- Using point-of-care technologies is an innovative way of providing testing access to communities that face challenges in accessing conventional laboratory services.

Availability of devices and supplies for point-of-care COVID-19 testing

- Scientists at the NML are working to find the best way to maximize availability of point-of-care testing supplies and develop a national distribution strategy to address the needs of Canada's most vulnerable.

- The Public Health Agency of Canada (PHAC) is committed to providing provinces and territories with a steady supply of COVID-19 tests. Due to global supply shortages, the existing supply of point-of-care testing devices and reagents remains limited.

- Once PHAC receives more devices and test cartridges and the required supplies are available, we will be able to look at gradually increasing the number of point-of-care tests administered.

Sample pooling

- Sample pooling is a testing strategy that involves mixing samples together in batches before inserting them into testing devices. If a batch tests negative, lab professionals can exclude all of the samples as negative. If a batch tests positive, each sample is tested individually to determine which samples in the batch are positive.

- Sample pooling is used to increase testing rates and conserve lab supplies. The challenge is ensuring that the results are always accurate (in terms of specificity and sensitivity). Before carrying out sample pooling, lab professionals must conduct studies to confirm result accuracy.

- Scientists at the NML have conducted studies and confirmed the accuracy of the results obtained from lab sample pooling for point-of-care testing devices used in clinical and remote settings. This is a major discovery in light of the global shortage of lab supplies for these devices, as pooling samples will help conserve resources.

Specific distribution plans

- As of September 30, the NML had distributed 105 testing devices and 34,000 test kits for use with the GeneXpert system to northern, remote and Indigenous communities.

- Devices are being distributed according to a needs analysis carried out with the provinces and territories and Indigenous Services Canada to ensure that the most vulnerable communities are equipped for COVID-19 outbreaks.

- Risk is assessed based on geographic isolation, distance from centralized labs and logistical challenges of transporting samples due to weather conditions and flight frequency. Risk assessments are also based on the demographic characteristics of community members, which determine who is most susceptible to complications from COVID-19.

Devices in the Northwest Territories

- On June 8, PHAC provided the Northwest Territories with two GeneXpert Quad testing devices and one 16-module GeneXpert system, as well as enough COVID-19 test cartridges for 160 tests.

- PHAC intends to continue supplying COVID-19 tests to the Northwest Territories on an ongoing basis. Due to the global shortage of point-of-care testing supplies, the company is still providing PHAC with limited resources. PHAC is in constant communication with

the Northwest Territories and the other provinces and territories with respect to their testing needs and practices.

Q&As

Q1: Why are there tests that have been approved in the United States but are not available in Canada?

Canada and the United States have different approval regulations and procedures. Each regulatory body reviews submissions based on its own requirements and criteria, which reflect the needs of its health care system.

Health Canada's consistent approach throughout the pandemic has ensured that the testing devices on the Canadian market are accurate and reliable. Canada has avoided some of the challenges that other countries have experienced with tests of poor quality.

Health Canada has proactively contacted a number of manufacturers of U.S.-authorized tests to solicit their interest in the Canadian market.

Under the Interim Order, Health Canada has been reviewing all COVID-19-related submissions as quickly as possible without compromising patient safety.

If pressed:

As a regulatory body, Health Canada is doing everything in its power to give Canadians and the health care system access to as many testing options as possible in a timely manner, without compromising on safety.

At Health Canada, we are closely monitoring emerging technologies. When we catch wind of promising new tests not yet available in Canada, we proactively contact the manufacturers to encourage them to enter the Canadian market.

Q2: Can provinces use tests that have not been authorized by Health Canada?

Yes. Provincial and territorial labs may develop their own tests on site and offer testing services.

Such tests and testing services are under provincial or territorial jurisdiction, as provinces and territories are responsible for the delivery and administration of health care services, including lab services.

Other labs wishing to use the mouth rinse and gargle sampling method implemented in British Columbia must confirm whether a sample collected by this method can be used with the lab's chosen testing device.

A lab's decision to use the mouth rinse and gargle method falls outside the scope of Health Canada's role as a regulatory body.

Health Canada will only intervene if a company is importing or selling test kits intended for use with mouth rinse and gargle samples. In this case, before granting authorization, Health Canada will ask the manufacturer for data confirming that such samples can be used with these kits.

Q3: Do saliva tests still use reagents to extract the virus from samples? Will this technology help alleviate some of the reagent shortages that sparked concern at the start of the outbreak? (answer approved by the NML)

The current saliva test rollout is not alleviating reagent-related pressures downstream. There are kits that could be put on the market and increase our reagent supply, but these kits are awaiting approval and rollout by public health labs.

The current rollout of saliva and mouth rinse and gargle tests has the potential to ease things on the human resources end by reducing the need for sample collection by trained health workers.

The National Microbiology Laboratory of the Public Health Agency of Canada is developing solutions for obtaining laboratory-extracted COVID-19 reagents mass-produced by New Brunswick-based company LuminUltra Technologies Ltd.

LuminUltra sent out its first batch of reagent on April 10, 2020. Under contract, the company will be manufacturing enough reagent for 500,000 tests per week until the end of March 2021. As of September 22, 2020, the company had manufactured enough reagent for over 11 million tests. The Government of Canada is actively working with the industry to identify Canadian alternatives to key inputs to increase testing capacity in Canadian labs. The aim is to ensure an adequate supply of required chemicals, including reagents, to avoid a bottleneck that would slow down Canada's testing strategy.

Q4: What is being done about testing capacity? Why do people have to wait so long to get tested? (answer approved by PHAC)

Each province and territory decides how to test its residents. Provincial and territorial testing strategies are guided by a common national testing approach as discussed by the Special Advisory Committee on COVID-19. Each day, PHAC shares how many people have been tested for COVID-19 in Canada.

The Government of Canada is investing $4.28 billion to help provinces and territories cover the cost of increasing their capacity to conduct testing, perform contact tracing and share public health data that will help fight the pandemic. The goal is to ensure provinces and territories have the capacity to test around 200,000 people per day, nationwide.