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 testing capacity as early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada. This is why Health Canada has prioritized the review of all types of COVID-19 tests, including new, innovative testing options and technologies.

- Health Canada is taking all steps available to us as a regulator to give Canadians and our health system access to as many testing options as possible, as quickly as we can, without compromising safety.
- Health Canada is closely monitoring new technology, and when we hear of promising new tests that are not yet available in Canada, we proactively reach out to manufacturers to seek their interest in entering the Canadian market.

- Furthermore, the Government of Canada is providing $4.28 billion to support provinces and territories with the costs 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 up to 200,000 people per day, nationwide.

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

- Canada has one of the best regulatory systems in the world for medical devices. Health Canada takes steps to ensure that the applicable safety, effectiveness and quality requirements are met for medical devices prior to issuing an authorization.

- Health Canada is currently reviewing submissions for point-of-care rapid tests, and will prioritize new and innovative testing options such as other rapid tests and home tests.

- Health Canada is working as quickly as possible toward the approval of rapid, point-of-care diagnostic and monitoring tests based on nucleic acid and antigen technologies in order to meet Canadian testing needs without compromising Canadians' safety.

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- The Government of Canada works proactively with companies that are developing innovative and new testing technologies in Canada and globally.

- You will find more information about testing here.

If asked about Abbott tests:

- The Abbott ID NOW COVID-19 test kit, which is the size of a toaster, can provide results within 13 minutes. Testing can take place in a variety of locations, such as medical clinics and nursing stations.

- Scientists at the NML are working closely with other federal, provincial and territorial partners to optimize point-of-care testing supplies and determine a national distribution strategy that will have the most benefit for Canadians.

- Once the devices are approved by Health Canada, the NML will provide training to support these testing devices. The NML will work with partners in the provinces and territories to verify the performance of the tests and provide best practice guidance on the use of these instruments.

- The NML offers ongoing support and technical advice for those using point-of-care devices in Canada. Part of this support is a robust quality assurance program to ensure that the devices are providing reliable results on a consistent basis.

If asked about other rapid test kits:

- On September 23, 2020, Health Canada authorized the *Hyris Global Diagnostics Kit* for point-of-care use.

- This point-of-care test should only be carried out by a trained health care professional.

- 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 (PHAC) National Microbiology Laboratory (NML) is working in collaboration with provincial and territorial public health laboratories to ensure high-quality diagnostic testing for COVID-19.

- Point-of-care diagnostic devices allow testing to occur in alternative healthcare settings and do not require shipping a specimen to a lab for analysis. This allows for quicker test results for patients.

- Quicker test results enable healthcare providers and patients to take appropriate actions, such as treating, contact tracing and isolating positive patients more rapidly to help reduce the spread of the disease.

- Point-of-care testing is essential for northern, remote and isolated communities, as well as specific high-risk settings where it is important to have test results quickly without having to send samples to a laboratory.

- Deploying diagnostic testing at the community level, especially in northern and isolated communities, will help address the testing gaps in underserved communities where laboratory testing is difficult to access.

- Health Canada authorizes point-of-care tests after completing a scientific review that is supported by evidence to ensure that the tests will provide accurate and reliable results. The NML and its provincial partners often contribute by assessing tests and sharing test results with Health Canada.

- A complete list of testing devices for use against COVID-19 is available on Health Canada's website: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19/diagnostic-devices-authorized.html.

If asked about antigen tests:

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

- On September 29, Health Canada published information for industry on the minimum sensitivity requirements that must be met when seeking authorization for COVID-19 antigen tests. Sensitivity is a measure of the diagnostic accuracy of a test.

- Health Canada is advising industry that they must provide evidence that clearly demonstrates that their antigen test meets a minimum standard of 80% sensitivity before it can be approved, so that the tests produce reliable results.

- Health Canada welcomes new technology and will prioritize applications for all types of test kits. Only tests that are proven to perform accurately and reliably will be authorized.

If asked about the British Columbia's "swish and spit" lab tests:

- "Swish and spit" is a new method of sample collection that has been developed by provincial health authorities and will be used in British Columbia as an alternative to the nasal swab, especially for collecting samples from children.
- Swish and spit samples are collected by rinsing a salt-water solution in your mouth and spitting the water mixed with your saliva into a cup.

- The "swish and spit" testing *process* is considered a lab-developed method, and is not subject to Health Canada oversight under the authority of the *Food and Drugs Act*.

- The sample *collection device* itself (i.e., the funnel in which the swish and spit sample is collected) is a Class I medical device that can be imported or sold under the authority of a Medical Device Establishment Licence, which is authorized by Health Canada.

- Health Canada and the Public Health Agency of Canada welcome all new technologies that will help in the fight against COVID-19 and reduce its impact on Canadians.

If asked about encouraging new device authorizations in Canada:

- Health Canada is actively engaging with manufacturers developing innovative and new testing technologies in Canada and abroad.

- Health Canada provides guidance on the regulatory process, and assists companies with their device submissions to help ensure that they submit the right information to be authorized promptly giving Canadians greater access to the tools they need in the fight of COVID-19.

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

If asked about sharing information about new device authorizations:

- Health Canada continually updates and posts new information on its website. For example, the Department recently provided updated information on home testing, and signalled that we welcome applications for all testing solutions.

Supplementary messages:

- We are committed to providing Canadians access to the tools they need to fight the spread of COVID-19 in Canada.

- Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.

- Health Canada is taking all steps available to us as a regulator to give Canadians and our health system access to as many testing options as possible, as quickly as we can, without compromising 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 available for sale in Canada have been accurate and reliable, and we have avoided some of the challenges other countries have experienced with lower-quality tests.

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

- The Minister of Health has provided authority that allows for faster access to tests for COVID-19 without compromising the quality, safety and efficacy of the device (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 has received two applications for saliva tests

using saliva (spit) but not the “swish and spit” process which includes a saline rinse.
- Saliva test applications have been prioritized and are currently under review.

If pressed on the authorization of Spartan test kits:

- Health Canada continues to work with Spartan Bioscience Inc. in its efforts to produce the evidence that demonstrates its product functions appropriately.

- Health Canada has provided regulatory guidance to Spartan Bioscience Inc. relating to the completion of clinical trials on its testing device and will prioritize the review of its application for authorization when it is received.

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

- Health Canada has not yet received any applications for at-home test kits, or to collect samples at home and mail them in for evaluation.

- Health Canada is aware that the U.S. Food and Drug Administration (FDA) approved the COVID-19 RT-PCR Test for which the collection of a fluid sample is done at home.

- The swab is collected at home and then sent to a laboratory for testing. The swabs are subject to strict transportation requirements.

- Canada and the U.S. have different rules and approval processes. Each regulator reviews applications against different criteria or requirements that reflect the needs of their health care systems.

- Health Canada’s consistent approach throughout the pandemic has ensured that the testing devices available for sale in Canada have been accurate and reliable, and we have avoided some of the challenges other countries have experienced with lower-quality tests.

- Other international regulators, including the U.S. FDA, have not approved complete at-home test kits for COVID-19.

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

If asked about the Health Canada’s June 2020 notice on near-patient and point-of-care diagnostic tests:

- Health Canada posted guidance for industry to clarify its position on near-patient and point-of-care diagnostic tests in June 2020. At that time, the Department’s position was in relation to the use of home tests for diagnostic purposes. In response to the evolution of the pandemic, Health Canada could now consider applications for self-collection and/or at-home test kits to enable individuals with or without symptoms who wish to assess and monitor their own infection status.

- Health Canada is open to reviewing all new testing solutions as they become available.

Specifics on the role of the NML

- NML is providing critical scientific leadership for Canada's response to COVID-19. This includes coordination with provincial and territorial governments and laboratories, as well as Indigenous Services Canada, to deploy point-of-care testing devices and supplies to rural and remote settings.

- NML scientists are exploring the best way to increase capacity of these devices through innovative testing approaches such as sample pooling.

- As of September 30, NML has conducted 40 remote and in-community training sessions for healthcare professionals who will be using the point-of-care devices.

- These training sessions provide valuable hands-on experience to those who will be operating the instruments.

- The NML offers ongoing support and technical advice for those using the devices. Part of this support is a robust quality assurance program to provide confirmation that the devices are providing reliable results on a consistent basis.

- NML has undertaken scientific studies of point-of-care diagnostic tests and supplies to support provincial laboratories in their decisions on adopting these tests for use in clinical settings. These studies are done in collaboration with provincial laboratories and clinical researchers to determine how well a test performs under actual clinical conditions. The test results are shared with Health Canada for consideration in the scientific review of applications for authorization under the Interim Order for Expedited Access to Medical Devices for COVID-19.

- Results on the performance of diagnostic tests are shared with manufacturing companies, all provincial laboratories, and Health Canada to add to the evidence on the accuracy of diagnostic tests.

- NML's priorities continue to be accessing testing reagents, evaluating rapid point-of-care tests, and accessing authorized test kits to help ensure that provinces and territories are equipped to ramp up testing according to their requirements.

What is a point-of-care diagnostic test?

- Point-of-care diagnostic tests are done at the time and place of care, such as a hospital or a doctor's office, and do not require samples to be sent to another laboratory.

- Molecular point-of-care tests to detect active infections of COVID-19 are similar to the polymerase chain reaction (PCR) tests used in regular laboratories as they also use a swab to collect samples from the nose or throat.

- Samples are then loaded into an on-site point-of-care device—an automated diagnostic testing device that detects DNA sequences—such as a GeneXpert or Abbott ID NOW instruments. For GeneXpert, the test results are ready in 30-60 minutes. For Abbott ID NOW, the test results are ready in 13 minutes. A laboratory professional is not needed to perform the test.

- Point-of-care technologies provide an innovative approach to accessing diagnostic testing services for communities and populations that experience challenges with conventional laboratory methods.

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On availability of COVID-19 point-of-care testing equipment and supplies

- Scientists at the NML are exploring the best way to optimize point-of-care testing supplies and determine a national distribution strategy to meet the needs of those most at risk.

- PHAC is committed to continuing to provide a supply of COVID-19 tests to provinces and territories on an ongoing basis. The current allotment of point-of-care test devices and reagents remains limited, as there is a global shortage of these supplies.

- Once PHAC receives an increase in devices and test cartridges and the necessary supplies become available, phased expansion of point-of-care testing can be considered.

On Sample Pooling

- Sample pooling is a diagnostic approach that involves grouping of samples in batches before running them through testing machines. If a negative result is received for the batch, laboratory professionals can rule out all the samples as having tested negative. If the batch tests positive, each sample is tested individually to determine the positive(s).

- Sample pooling is an approach used to increase throughput and conserve laboratory supplies. The challenge is to ensure that results are still accurate (i.e., specific and sensitive). Laboratory professionals must conduct research studies to confirm accurate results before sample pooling is implemented.

- NML scientists have conducted research studies and have verified that pooling laboratory specimens for point-of-care devices used in remote and clinical settings provides accurate results. This is a very important discovery as there is a global shortage of laboratory supplies for these devices and pooling will help extend resources.

On specific deployment plans

- As of September 30, the NML has deployed 105 testing devices and over 34,000 COVID-19 tests for use across Northern, remote, and Indigenous communities.

- The devices are being deployed based on a needs analysis—in coordination with provinces and territories and Indigenous Services Canada—to get devices to communities that are at greatest risk if there were to be an outbreak of COVID-19.

- The risk is assessed based on remoteness, proximity to centralized laboratories, and logistical challenges with transporting samples due to weather and frequency of flights. Risk assessments are also based on the demographic of community members for those at greatest risk of COVID-19 complications.

On Devices in Northwest Territories

- As of June 8, PHAC has provided two GeneXpert Quad point-of-care testing devices and one 16-channel GeneXpert testing device to the Northwest Territories (NWT), along with a supply of test cartridges (160 tests) for COVID-19.

- PHAC is committed to continuing to provide a supply of COVID-19 tests to NWT on an ongoing basis. The current allotment from the company to PHAC remains limited, as there is a global shortage of point-of-care testing supplies. PHAC maintains a regular dialogue with NWT, and the other provinces and territories, regarding their testing needs and practices.

Questions and Answers:

Q1. Why are there tests that have been approved in the U.S. that are not available in Canada?

Canada and the U.S. have different rules and approval processes. Each regulator reviews applications against different criteria or requirements.

Health Canada's consistent approach throughout the pandemic has ensured that the testing devices available for sale in Canada have been accurate and reliable, and we have avoided some of the challenges other countries have experienced with lower-quality tests.

Health Canada has proactively contacted numerous manufacturers of tests authorized in the U.S. to seek their interest in entering the Canadian market.

Health Canada has reviewed all COVID-19-related submissions under the Interim Order as quickly as possible without compromising patient safety.

If pressed:

Health Canada is taking all steps available to us as a regulator to give Canadians and our health system access to as many testing options as possible, as quickly as we can, without compromising safety.

Health Canada is closely monitoring new technology, and when we hear of promising new tests that are not yet available in Canada, we proactively reach out to manufacturers to seek their interest in entering the Canadian market.

Q2. Is it OK for provinces to use tests that have not been authorized by Health Canada?

Yes. Provincial and territorial laboratories can develop their own tests in-house and offer testing services.

These tests and testing services are regulated under provincial or territorial jurisdiction, as they are responsible for the delivery and administration of health care services, which includes laboratory services.

If another laboratory wishes to use the "swish and spit" sample method being introduced in British Columbia, the laboratory would also have to validate the use of the sample with their chosen diagnostic device.

This decision by the laboratory to use the "swish and spit" method remains outside the purview of Health Canada's regulatory role.

Health Canada would only become involved if a company were to import or sell a diagnostic kit indicated for use with a “swish and spit” sample. In that case, we would request data validating the use of that sample with the kit from the manufacturer prior to obtaining HC authorization.

Q3. Does saliva based testing still use reagents to extract the virus from the sample? Will this technology alleviate some of the shortages on reagents that were a concern during the early days of the outbreak? (NML approved answer)

The current implementation of saliva-based tests does not alleviate any downstream reagent pressures. There are some potential kits coming to market that may add reagent capacity, but that is pending approval and implementation by public health laboratories.

The current saliva and ”swish and spit” implementation does provide potential relief on the human resources side since it reduces the need for trained health care workers to collect samples.

There is a global shortage of many of these reagents, and this affects laboratory capacity. We need made-in-Canada solutions to tackle this problem. Securing domestic capacity ensures Canada has the supply it needs to meets its testing needs.

The Public Health Agency of Canada’s (PHAC) National Microbiology Laboratory has been developing solutions to secure COVID-19 laboratory extraction reagents, which is being mass-produced by Luminultra Technologies Ltd., a New Brunswick-based company.

LuminUltra shipped its first batch of reagent on April 10, 2020, and is under contract to manufacture reagents for up to 500,000 tests a week until the end of March 2021. As of September 22, 2020, they have produced enough reagents for more than 11 million tests.The Government of Canada has been actively working with industry to identify domestic alternatives for key inputs to grow domestic lab-based testing. These efforts focus on ensuring sufficient capacity of necessary chemicals—including reagents—to avoid a bottleneck in Canada’s testing strategy.

Q4. What is being done about testing capacity? Why are there such long waits to get tested? (PHAC approved content for response)

Each province and territory decides how to test residents. The testing strategies in the provinces and territories are guided by a common, national approach to testing, as discussed under the COVID-19 Special Advisory Committee. PHAC publishes the number of people tested in Canada every day.

The Government of Canada is providing $4.28 billion to support provinces and territories with the costs 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 up to 200,000 people per day, nationwide.