

Media Lines

Health Canada authorization of COVID-19 in vitro testing devices

Issue Statement: As of June 18, Health Canada has issued authorizations for the sale of five serological tests in Canada under the Interim Order process. On June 17, the Government of Canada finalized a contract with Abbott Laboratories for 140,000 serological test kits, which will be used for research studies under Canada's [Immunity Task Force](#).

Key Messages:

- Following scientific review, Health Canada has now authorized the sale of five serological tests:
 - DiaSorin LIAISON® test (authorized May 12)
 - Abbott ARCHITECT SARS-CoV-2 IgG Assay (authorized May 14)
 - Roche Elecsys Anti-SARS-CoV-2 (authorized June 5)
 - Ortho Clinical Diagnostics VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack (authorized June 8)
 - Abbott Laboratories Diagnostics Division SARS-CoV-2 IgG (authorized June 11)
- Serological tests are authorized to detect antibodies specific to the virus. Serological tests provide evidence of a previous exposure to the virus that causes COVID-19 by testing for the presence of antibodies.
- Health Canada authorized the tests after completing scientific reviews that were supported by evidence to ensure that the tests will provide accurate and reliable results.
- A complete list of testing devices for COVID-19 is available on Health Canada's [website](#).
- Serology testing will contribute to a better understanding of the immune status of those who have been infected.
- Using validated and effective serological tests for COVID-19 will be an important step in Canada's public health response.
- Serological surveys can also help guide important public health decisions once a vaccine becomes available.
- Health Canada will continue to focus on the health and safety of Canadians while expediting the supply of safe and effective health products related to COVID-19.
- The Government of Canada has finalized a contract with Abbott Laboratories for 140,000 serological test kits.
- These kits can detect the presence of previous exposure to COVID-19 and will be used for research studies that are being coordinated by the [Immunity Task Force](#).
- Serological tests will play an important role in tracking how widely the virus has spread.
- Information made available through the results of these serological test kits could also prove valuable in the estimation of potential immunity and vulnerabilities in our population.

[APG]

- On April 23, the Government of Canada launched the COVID-19 Immunity Task Force to lead a Canada-wide unified effort to test blood samples for signs of COVID-19 infections.
- The Immunity Task Force is also working with an Indigenous Advisory Circle with representatives from Indigenous communities across the country to identify a specific approach to immunity testing in Indigenous communities.

Supplemental messages:

- These tests must be carried out in a laboratory setting.
- Serology-based tests are essential to understanding the immune response to virus infection and will play a key role in determining the extent of exposure to the virus through sero-surveillance studies.
- Further research is required to fully comprehend the relationship between positive antibody tests and protection against re-infection.
- In accordance with Health Canada's [Guidance on serological tests](#), a condition is applied to the authorization issued to serology-based tests in order to monitor the ability of the test to perform as intended once in use by the Canadian health care system.
- Serology-based tests should be used in conjunction with the testing strategy outlined by municipal, provincial or territorial public health authorities.
- Nucleic acid-based tests are the only authorized testing devices in Canada to diagnose an active infection with COVID-19.

If pressed on Canada's approach to authorizing COVID-19 testing devices

- As an emergency public health measure, the Minister of Health signed an Interim Order to allow expedited access to COVID-19-related medical devices, including testing devices.
- Only testing devices authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results.
- Health Canada has confirmed that authorized COVID-19 tests are well supported by evidence that they will provide accurate and reliable results. More than 20 COVID-19 testing devices are now accessible in Canada. The list of authorized testing devices is posted on [Health Canada's website](#).
- Canada has maintained a science-informed approach to managing the pandemic, including maintaining requirements for pre-market authorization of testing technologies.
- Providing the Canadian population and individuals with accurate information about infection status is a pillar of the country's response to the pandemic.

[APG]



- Health Canada's position on the use of serological assays is in line with the [World Health Organization's view](#) that serological assays will play an important role in research and surveillance.
- The Public Health Agency of Canada's National Microbiology Laboratory (NML) and its partners are working on assessing a variety of commercial serological tests for the SARS-CoV-2 virus. 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 implementation of serologic testing across Canada.
- Health Canada continues to review other serological technologies in accordance with its Guidance on serological tests. Health Canada will authorize other serological tests that show high sensitivity and specificity. For additional information, please consult the [serological testing devices for use against COVID-19](#).

If pressed on the Public Health Agency of Canada's National Microbiology Laboratory's (NML) review:

- As part of its research efforts, the Public Health Agency of Canada's NML performs scientific reviews of new medical devices.
- In response to the urgent nature of COVID-19, the NML is being asked by companies to perform scientific review and assess the performance of medical supplies, such as COVID-19 test kits.
- NML reviews these COVID-19 medical supplies to ensure they meet the gold standard used in public health laboratories and can be used to obtain reliable and accurate results.
- This test verification function is part of scientific research and is independent of Health Canada's regulatory approval process. While this assessment is separate from Health Canada's authorization process, the NML works closely in collaboration with Health Canada to share knowledge gained through the review process.

If pressed on what serological testing means for Canadians

What is serological testing used for?

Serology-based tests are essential to understanding the immune response to virus infection. They will play a key role in determining the extent of exposure to the virus through sero-surveillance studies.

Serological testing is not authorized to diagnose COVID-19 infections because it detects antibodies produced by the patient's immune response. Those antibodies are not likely to develop until later in the infection, thereby giving false negative results in many cases. For diagnostic testing, authorized devices test directly for the actual virus while infections are occurring, using molecular tests with swabbed specimens.

How will the results of serological testing be used?

[APG]

Using validated and effective serological tests for COVID-19 will be an important step in Canada's public health response.

On April 23, the Government of Canada launched the COVID-19 Immunity Task Force to lead a Canada-wide unified effort to test blood samples for signs of COVID-19 infections.

Rapid and representative national surveys will provide a snapshot of where we stand now, and what to expect in a possible second wave of infection. They can also shed light on the potential immune status of vulnerable populations such as Indigenous communities, and residents of nursing homes and long-term care facilities.

Serological surveys can also help guide important public health decisions once a vaccine becomes available.

Is the government considering the possibility of serological or immunity passports or certificates to allow people with immunity to move freely again?

There is an active international effort to assess whether those who have recovered from illness are safe to resume daily activities.

More research is needed before making decisions in Canada.

Other respiratory viruses generally do not provide an individual with 100% immunity after recovery.

Right now, we just do not know whether individuals who have recovered from COVID-19 will have immunity, how long that immunity may last, or whether it's possible for individuals to experience less severe or potentially more serious illness if they get COVID-19 a second time.

Additional Questions and Answers:

Q1. How is Canada currently testing patients who are suspected to have COVID-19?

Provinces and territories conduct diagnostic testing for the virus that causes COVID-19. Canada's National Microbiology Laboratory works in collaboration with provincial public health laboratories to ensure high-quality diagnostic testing according to laboratory standards.

Q2. How will Health Canada ensure that test kits are safe and effective?

The Interim Order creates a tailored approval pathway for the importation and sale of medical devices that support Canada's response to COVID-19. This Interim Order, and the tailored approval pathway it creates, provides the Minister with flexibility to consider the urgent circumstances relating to the need for the medical device, authorizations granted by foreign regulatory authorities, or possible new uses for medical devices that are already approved in Canada.

As with all drugs and medical devices, Health Canada assesses and monitors the safety and effectiveness of all products authorized under this Interim Order, and will take immediate action if required to protect the health and safety of Canadians.

[APG]

Manufacturers are still required to follow strict post-market safety requirements such as mandatory problem reporting, recall procedures and complaint handling.

Q3. Why did it take so long for Health Canada to authorize a serological test?

Providing the Canadian population and individuals with accurate information about appropriate public health measures and infection status is a pillar of the country's response to the pandemic. Canada has maintained a science-informed approach to managing the pandemic including maintaining requirements for pre-market authorization of COVID-19-specific tests.

Health Canada authorized the test after completing a scientific review that was supported by evidence to ensure that the test will provide accurate and reliable results. More than 20 COVID-19 testing devices are now accessible in Canada. The list of authorized testing devices is posted on [Health Canada's website](#).

If pressed:

- Each public health laboratory across Canada will decide whether it wants to use authorized serological tests, based on its own needs and scientific review and requirements.

Q4. Is the federal government releasing guidelines to provinces on how to conduct antibody testing?

PHAC and Health Canada do not develop guidelines or directives on which kits to use/not use specifically, or by name. PHAC provides evaluation results and could provide some interpretation of those results.

[APG]