Health Canada Santé Canada

Media Lines

Health Canada authorization of COVID-19 in vitro testing devices

Issue statement: On May 12, Health Canada issued the first authorization for the sale of a serological test in Canada under the Interim Order process.

On May 14, the Department authorized the sale of another serological test in Canada under the Interim Order process.

Key messages

- Following scientific review, Health Canada has now authorized the sale of two new serological tests: the DiaSorin LIAISON® test (authorized on May 12) and the Abbott ARCHITECT SARS-CoV-2 IgG Assay test (authorized on May 14).

- Both 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.

- The full list of authorized medical devices for uses related to the coronavirus can be found on the Health Canada web site at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html.

- 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.

Supplementary 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 reinfection.

- 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 a dozen 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.

- 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 page.

If pressed on the validation of test kits by the NML

The Public Health Agency of Canada's National Microbiology Laboratory does not validate medical devices, such as swabs or test kits, as part of its normal activities. However, it does assess whether these can be used for testing as part of its research activities.

Given the urgency of the situation, at the request of companies, the NML assesses the effectiveness of diagnostic devices, such as test kits and 3D-printed swabs. The NML reviews COVID-19 laboratory supplies for clinical diagnostic purposes to ensure they meet the gold standard used in public health laboratories.

This validation process is to determine if the product can be used to obtain reliable and accurate results when diagnosing COVID-19. Although the process is separate from Health Canada's scientific review process, the NML works with the Department's Medical Devices Directorate to pool the knowledge acquired as part of the review process.

Health Canada regulates the sale and importation of medical devices in Canada. Unauthorized medical devices can yield inaccurate results, which can result in misdiagnosis. The accuracy and reliability of COVID-19 test authorized by the Department are well established.

If pressed on the scientific review of the DiaSorin LIAISON® test and Abbott ARCHITECT SARS-CoV-2 IgG Assay test

- Health Canada has completed the scientific review of the DiaSorin LIAISON® and Abbott ARCHITECT SARS-CoV-2 IgG Assay serological tests as part of the Interim Order authorization process.

- The two tests are being authorized under the Interim Order under certain conditions, namely:
    - submission to Health Canada of a plan to assess the effectiveness of the test when used in the specified facilities, including at least two Canadian facilities;
    - submission of a summary of other cross-reactivity studies;
    - submission of a reagent stability report.

- The validity of the Abbott ARCHITECT SARS-CoV-2 IgG Assay test was demonstrated through an evaluation performed using samples from 31 infected individuals and 1,070 negative samples.
    - Other validation results from the University of Washington confirming the data provided by the company have been found in the literature.

- The validity of the DiaSorin LIAISON® test was demonstrated through an evaluation performed using samples from a number of facilities in Italy and France.
    - Other validation results confirming the data provided by the company have been submitted by the British Columbia provincial laboratory.

- Health Canada will continue to work with the NML and other public health laboratories in Canada to study relevant results obtained as part of their validation processes and their use of testing devices.

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 though 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?

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 established the COVID-19 Immunity Task Force to oversee Canada-wide effort to screen blood samples for COVID-19.

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 possible immune status of vulnerable populations and individuals, including Aboriginal communities and residents of nursing and long-term care homes.

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.

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 tests after completing scientific reviews that were supported by evidence to ensure that the tests provide accurate and reliable results. More than a dozen 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 scientific review and assessment of its needs and requirements.