

Media Lines Antigen Testing for COVID-19

Issue Statement:

The Public Health Agency of Canada is publishing [guidance on antigen testing](#) that will be posted to Canada.ca, along with some additional web content.

Key messages:

- Testing is a key pillar of Canada's response to the COVID-19 pandemic, enabling the detection and public health management of cases and their contacts.
- Antigen testing is one of several emerging technologies that can be used to determine if a person presenting symptoms is infected with the COVID-19 virus.
- An antigen test for COVID-19 involves collecting samples from a patient's nose or throat using a swab.
- The main advantage of an antigen test for COVID-19 is that a patient can have their results within about 15 minutes. However, antigen tests are usually less sensitive than molecular polymerase chain reaction (PCR) tests for COVID-19 detection so they are less accurate.
- To respond to a growing need for a variety of tests, the Government of Canada along with territorial and provincial partners is finalizing *Interim Guidance on the Use of Rapid Antigen Detection Tests for the Identification of SARS-CoV-2 Infection*. This guidance provides information on the use of rapid antigen detection tests (RADT) for SARS-CoV-2 in the context of the public health system. This guidance should be finalized in the coming days.
- Health Canada is reviewing submissions for antigen tests. For more information, please consult our [list of testing device applications under evaluation](#).
- Molecular polymerase chain reaction (PCR) testing is the gold standard used in Canada and abroad to diagnose and confirm active COVID-19 infection in patients with symptoms.

If pressed on the Public Health Agency of Canada's National Microbiology Laboratory's review of antigen test kits

- As part of its research efforts, the Public Health Agency of Canada's National Microbiology Laboratory's 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 reviews](#) and to assess the performance of diagnostic supplies such as COVID-19 testing kits.



- The NML reviews these COVID-19 laboratory supplies for clinical diagnostic to verify that they perform in a way that meets quality standards used in public health laboratories and can be used to obtain reliable and accurate results when diagnosing COVID-19.
- 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 in collaboration with Health Canada to share knowledge gained through the review process.

If pressed on the Interim Guidance on the use of Antigens for Detection of SARS-CoV-2

- This document provides interim guidance on the use of antigen-based testing for SARS-CoV-2.
- This is a rapidly evolving field as new tests and technologies come to market and data on performance and utility increase.
- These guidelines will be periodically updated as the science evolves.

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.
- Health Canada is advising industry that they must provide evidence which clearly demonstrates that their antigen test meets a minimum standard of 80% sensitivity/accuracy before it can be approved.
- 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.

Q1. What scenarios might be appropriate for COVID-19 antigen testing in Canada?

- Antigen testing may have a future role to play in avoiding large cluster outbreaks of COVID-19 in Canada.
- Antigen testing may also be of value to residents of remote or isolated communities. Results could be available at a testing site, such as a doctor's office, within a few minutes.
- Antigen tests may also have a role in settings where repeated testing may be appropriate.
- Settings where routine testing is not currently taking place could benefit most from antigen testing for COVID-19.

Q2. What is the accuracy rate of antigen tests for COVID-19 in Canada?

- The Government of Canada is reviewing submissions for antigen tests. The accuracy rates of these tests under review is still unknown; however, Health Canada is advising industry that they must provide evidence which clearly demonstrates that their antigen test meets a minimum standard of 80% sensitivity/accuracy before it can be approved.
- There is limited published scholarly data available on the performance of antigen testing for COVID-19.
- Based on how the technology works, antigen tests are likely to perform best in the early phase of disease, within a few days of symptom onset.

Q3. Are antigen tests cheaper than PCR tests?

- Yes, in many countries, antigen tests are cheaper than PCR tests; however, because they are not currently approved for sale in Canada, we do not have a price point to refer to at this time.
- Only tests authorized by Health Canada can be legally imported or sold in Canada.