

COVID-19 CADTH HORIZON SCAN

Rapid Point-of-Care Antigen Testing for SARS-CoV-2 Infection

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To produce this report, CADTH used a modified approach to the selection, appraisal, and synthesis of the evidence to meet decision-making needs during the COVID-19 pandemic. Care has been taken to ensure the information is accurate and complete, but it should be noted that international scientific evidence about COVID-19 is changing and growing rapidly.

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How It Works

Antigen tests for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19 disease, use lateral flow immunoassays to detect the presence of viral proteins and identify a current infection.^{1,2} The tests require a sample to be collected with a swab from inside the nose or back of the throat.¹ After collection, the swab is mixed in a liquid reagent, which is then applied to the testing device.¹ Rapid antigen testing is not new. These types of tests are used for point-of-care (PoC) diagnoses of other respiratory illnesses like influenza, respiratory syncytial virus, and pneumonia, as well as other infections such as group A streptococcus and malaria.³ There are different ways of interpreting the results of rapid antigen tests. Some use devices similar to pregnancy tests that visually display a positive or negative result,⁴⁻⁸ while others require the use of bench-top⁹ or hand-held¹⁰ analyzers to display and interpret the results of the test.

These tests are being developed for rapid use at the PoC, which means that they can be used in a health care setting like a doctor's office, pharmacy, or assessment centre and the samples do not need to be sent to a lab to be analyzed.¹¹ The tests are generally easy to use, can be done by the trained health care workers at the site, and results can be obtained quickly, usually in about 30 minutes.¹¹ Depending on testing volume, it may take a day or longer to receive results from lab-based tests.¹² Faster results mean people with positive tests can be isolated more quickly and contact tracing can begin in a shorter time span.

Who Might Benefit?

The use of rapid PoC antigen testing has the potential to benefit a wide range of people. The ease of use and short turnaround time means more people could be tested more quickly, potentially resulting in less productive time lost to waiting for tests and for results. More rapid testing could also lead to more frequent testing, allowing people with positive results to be identified in the earlier stages of infection.² Isolating those who test positive early in the infectious period, and initiating contact tracing immediately, could potentially decrease the rate of community transmission. Using PoC testing has the potential to free up labs to do confirmatory reverse transcription polymerase chain reaction (RT-PCR) diagnostic testing rather than it being used to monitor broad populations of asymptomatic people who want to get tested as a precaution before returning to school or work, or before travel. Overall, more testing options provide the opportunity for a greater proportion of the population to be tested and help to curb the spread of the virus.

Availability in Canada

As of October 15, 2020, two rapid PoC antigen tests (PANBIO COVID-19 Ag Rapid Test Device⁹ and BD Veritor System For Rapid Detection of SARS-CoV-2¹⁰) are authorized for use in Canada.¹³ Five antigen tests (Sofia 2 SARS Antigen FIA,⁹ SD Biosensor STANDARD Q COVID-19 Ag,⁵ Sona Nanotech Covid-19 lateral flow assay,⁷ Rapid Response Covid-19 Antigen Rapid Test Device¹⁴ and BIOCREDIT COVID-19 Ag⁶) have been received for evaluation by Health Canada for screening or monitoring of SARS-CoV-2 infection.¹⁵

Six rapid PoC antigen tests have received Emergency Use Authorization (EUA) from the FDA.¹⁶ These tests include the BinaxNOW COVID-19 Ag Card (Abbott),¹⁷ LumiraDx SARS-CoV-2 Ag Test,¹⁸ BD Veritor System for Rapid Detection of SARS-CoV-2,¹⁰ Sofia SARS Antigen FIA (Quidel)⁹ [Sofia 2 Flu + SARS Antigen FIA](#) (Quidel),¹⁹ and CareStart

COVID-19 Antigen test (Access Bio Inc.).²⁰ The FDA requires that antigen tests have a sensitivity of at least 80% in order to be considered for EUA.²¹ These tests have been authorized for use for diagnostic testing on people with symptoms of COVID-19 within five to seven days of the beginning of their symptoms.²

What Does It Cost?

No data were available regarding the potential costs of these tests in Canada.

In the US, the Abbott BinaxNOW COVID-19 Ag Card will cost US\$5 per test when it becomes available.⁴ This test can be used in combination with a free mobile app that provides the individual with access to their most current test results.¹⁷ The BD Veritor system costs approximately US\$300 and an additional US\$20 per test conducted.²² No cost information was available for the LumiraDx or Sofia testing systems.

Current Practice

RT-PCR testing is the current standard for the diagnosis of COVID-19 in Canada.¹² RT-PCR testing looks for the presence of viral genetic material in the diagnostic sample and is done by trained professionals in a lab. Swab samples are taken from the nose or throat, then shipped to a lab and processed.¹² The turnaround time to receive the test results ranges from one to three days and may depend on testing volume.¹² A positive test means that the person tested currently has COVID-19.¹² Some PoC RT-PCR tests are available in some rural, remote, and isolated communities or in some high-risk areas, where faster test results are required.¹²

In September of 2020, the US Centers for Disease Control and Prevention² (CDC) and the WHO²³ released interim guidance on the use of antigen testing for SARS-CoV-2. Health Canada released interim guidance on the use of rapid antigen detection tests for the identification of SARS-CoV-2 infection in October of 2020.²⁴ Because RT-PCR testing remains the standard for COVID testing, the results of rapid antigen tests may sometimes need to be confirmed with RT-PCR testing.^{2,24} The guidance suggests that clinicians can generally rely on positive diagnostic antigen tests because the specificity of the tests (specificity is the test's ability to correctly identify a negative sample; a test with high specificity does not often produce a positive result for someone who is negative for the virus) with current EUA is high when used to test people with visible symptoms of COVID-19.² The WHO guidance specifies a sensitivity of 80% or greater and a specificity of 97% or greater is required for an antigen test to be used for the diagnosis of SARS-CoV-2.²³ Because of the lower sensitivity of antigen tests (sensitivity is a test's ability to correctly identify a positive sample; a test with lower sensitivity is more likely to report a negative result for someone who does in fact have the virus), negative test results in a person with symptoms or with a known exposure to confirmed COVID-19 may need to be confirmed by RT-PCR testing.²

Per the interim guidance, rapid antigen tests have the potential to be used as a screening tool in group settings, such as long-term care or correctional facilities, where serial testing could result in the earlier identification and isolation of a potential positive and prevent an outbreak and further transmission within the facility.^{2,23} In this case, the positive result would be considered presumptive and would be confirmed with an RT-PCR test if the person is not symptomatic or there has not been a known exposure to COVID-19.² Rapid antigen testing

may also provide the opportunity to monitor for infection after a known or suspected exposure, potentially leading to reduced isolation times.

What Is the Evidence?

A living diagnostic review of rapid, PoC antigen and molecular-based tests for the diagnosis of SARS-CoV-2 infection identified five studies (eight evaluations) of five antigen tests.¹ The quality of the studies was reported as low and the authors' confidence in the evidence was limited.¹ The average sensitivity was 56.2% (95% CI, 29.5% to 79.8%) and the average specificity was 99.5% (95% CI, 98.1% to 99.9%).¹ The studies identified in the living review did not include evaluations of the rapid PoC antigen tests that have received FDA EUA or that are currently under consideration by Health Canada.

Other Information

Clinical studies were not identified evaluating the efficacy of the six FDA-authorized antigen tests. Their sensitivity and specificity were identified from product brochures.

Table 1: Sensitivity and Specificity of FDA Authorized Antigen Tests

Test	Reported sensitivity (%)	Reported specificity (%)
BinaxNOW COVID-19 Ag Card ²⁵	97.1	98.5
LumiraDx SARS-CoV-2 Ag Test ²⁶	97.6	96.6
BD Veritor System for Rapid Detection of SARS-CoV-2 ²⁷	84	100
Sofia SARS Antigen FIA ²⁸	96.7	100.0
CareStart COVID-19 Antigen test ²⁹	83.8	100.0
Sofia 2 Flu + SARS Antigen FIA ¹⁹	95.2	100.0

A non-peer-reviewed pre-print was identified reporting a study comparing the BD Veritor system to both RT-PCR and the Sofia SARS Antigen FIA.³⁰ The authors found that the two PoC tests had high positive, negative, and overall agreement of results when compared with each other (97.4%, 98.1%, and 98.1%, respectively).³⁰ Positive percent agreement between the Veritor system and RT-PCR ranged from 81.8% to 87.5%.³⁰

Real-world evaluations comparing the results of antigen tests with RT-PCR testing are under way.³¹

Safety

The rapid PoC antigen tests have been shown to have a lower sensitivity than the RT-PCR test. That means there is a higher chance of a false-negative result, which is a negative test result in a person who is positive for the virus.¹² This can happen when the test is performed too soon after exposure to the virus and there is not enough viral antigen in the sample to result in a positive test.¹² False-negative tests may result in further spread of the virus by people who have received a negative test result despite being unknowingly infectious to others.¹²

No safety issues have been reported related to the collection of the testing sample, although some people do experience discomfort from the deep nasal swab.

Issues to Consider

There have been some hesitations about adopting lower sensitivity tests as a diagnostic tool because of the potential for false-negative results and the unintentional spread of SARS-CoV-2. While antigen testing is generally less sensitive than RT-PCR RNA testing, these tests might be useful as a screening or monitoring tool, as they are inexpensive, fast, and could be administered often.³² The CDC has indicated that the tests are sensitive to high viral loads and people with asymptomatic infection are likely at the highest risk of spreading SARS-CoV-2 without realizing it.³² More frequent testing of asymptomatic individuals could result in infectious cases being isolated sooner and potentially preventing further spread. Screening tests for SARS-CoV-2 could be especially helpful in large group settings such as long-term care homes, correctional facilities, workplaces, or schools.²

Related Developments

There are a variety of other testing methods and settings being studied. An ultra-sensitive, rapid lab-based antigen test has been developed that uses blood sampling and relies on single molecule array technology.³³ This test may be able to help clinicians identify which hospitalized patients with COVID-19 are most likely to experience severe disease.³³

Some research has been done into the feasibility of using saliva samples instead of nasal or throat swabs for PoC antigen testing.³⁴ Saliva samples were shown to produce similar results with easier sample collection.³⁴ Other saliva-based testing is being evaluated that is less uncomfortable for the recipient to take and also has the potential for self-collection, which could help reduce the exposure of health care workers.³⁵ The FDA has now granted EUA to five saliva-based tests, including the test being used in the NBA bubble.³⁶

At the University of South Florida, pooled saliva samples are being used to test groups of athletes prior to competition.³⁷ About 98% of SARS-CoV-2 tests conducted in Canada have produced negative results.³⁸ Pooled testing may be a way to reduce the number of tests and waste associated with negative tests while still accurately capturing positive tests.

Two Canadian airlines are participating in pilot projects of voluntary rapid testing for people arriving at Canadian airports.³⁹ A similar program is in place at the airport in Frankfurt, Germany.³⁹

Health Canada has indicated it is open to reviewing all testing solutions, including self-collected or at-home tests.¹¹ These types of tests would allow people with or without symptoms to assess and monitor their infection status as often as they felt necessary.¹¹ In the US, the development of an at-home, self-administered antigen test is under way.⁴⁰ Developers indicate that the test will be paired with a mobile app that will provide instructions on how to self-collect a nasal swab and administer the test. It will then use artificial intelligence to interpret the test results and the app will automatically send test results to local health authorities and link with electronic health records.⁴⁰

Looking Ahead

Some rapid tests are authorized in Canada and the US, though the effectiveness and accuracy of these tests has not been fully assessed in clinical trials. More study is required to determine how well these tests work in real-world scenarios. As with all things related to COVID-19, testing is evolving rapidly. More PoC antigen and other tests for the diagnosis of SARS-CoV-2 are under development and will likely be submitted to regulators for review in the near future.⁴¹

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