

COVID-19 CADTH Horizon Scan

# At-Home Testing for Severe Acute Respiratory Syndrome Coronavirus 2

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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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**Author:** Michelle Clark

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## COVID-19 Testing Will Soon Be Possible at Home

It has been more than a year since the beginning of the COVID-19 pandemic and diagnostic test manufacturers have since developed tests to detect severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, the virus that causes COVID-19 disease. These tests can be purchased without a prescription and can be self-administered at home.

### How It Works

Molecular and antigen tests are used for the detection of a current infection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19 disease. Reverse-transcriptase polymerase chain reaction (RT-PCR) and real-time loop-mediated amplification (LAMP) are the 2 types of molecular tests being used for COVID-19 testing. Each type of test identifies a different target — either viral genetic material or surface proteins — and can best be used at different points in the course of infection. Tests are evaluated based on their sensitivity (a test's ability to correctly identify the target that is indeed present in a person's sample) and specificity (the test's ability to correctly identify when there is no target in a sample). The higher the sensitivity and specificity values, the more confident we can be in the accuracy of the results of the test.

RT-PCR testing is considered the gold standard in the diagnosis of an active SARS-CoV-2 infection.<sup>1</sup> RT-PCR testing looks for the presence of viral genetic material in the diagnostic sample and is usually done by trained professionals in a lab or at the point of care (POC).<sup>2</sup> These tests convert single-strand samples of ribonucleic acid, or RNA, into double-stranded DNA and then amplify the DNA into larger quantities that are easier for the test to detect.<sup>3</sup>

LAMP tests work in a similar way but use enzymes instead of heat to separate the 2 strands of DNA.<sup>3</sup> The lack of reliance on thermal cycling and nucleic acid extraction makes for a simpler test that can be adapted more easily for POC and at-home use.<sup>3</sup> To administer the at-home tests, individuals need to collect their own nasal swab samples, then stir the swabs in reagent to create the samples to be analyzed by the test. For LAMP tests, the vial is inserted into the testing unit and the results will be displayed on the testing unit.<sup>4</sup> A positive result can be confirmed in as few as 11 minutes and a negative result in 30 minutes.<sup>5</sup>

Antigen tests for SARS-CoV-2 generally use lateral flow immunoassays to detect the presence of viral proteins to identify a current infection.<sup>3</sup> The use of these types of tests is established for POC diagnoses of other respiratory illnesses such as influenza, respiratory syncytial virus, and pneumonia, as well as other infections such as group A streptococcus and malaria.<sup>3</sup> Antigen tests are generally less sensitive than RT-PCR testing. For this reason, they may be more likely to miss a case of COVID-19 and may be more appropriate for screening and monitoring the spread of SARS-CoV-2 rather than diagnosing COVID-19.<sup>2</sup> For antigen tests, the reagent containing the nasal sample is applied to the testing unit itself and a combination of lines corresponding to the result will appear on the testing unit for visual interpretation, similar to how the results of a pregnancy test are displayed.<sup>3</sup>

The tests that have so far been developed for at-home use in North America are based on LAMP (Lucira Check-It COVID-19 Test Kit)<sup>6</sup> and antigen (Ellume COVID-19 Home Test, BD Veritor System for Rapid Detection of SARS-CoV-2, QuickVue At-Home OTC COVID-19 test, BinaxNOW COVID-19 antigen self-test, Abbott Panbio COVID-19 Antigen Rapid Test)<sup>7</sup> technologies.

## Who Might Benefit?

The use of rapid, at-home, COVID testing has the potential to benefit a wide range of people. The ability to use these tests at home without the supervision of a health care professional, and with a short turnaround time, means more people can be tested more quickly, potentially resulting in less productive time lost to waiting for tests and for results. At-home tests can provide accurate results in less than 30 minutes compared with 1 or more days for laboratory testing results.<sup>3</sup> The development of affordable and accurate at-home testing could lead to more frequent testing, allowing people with positive results to be identified in the earlier stages of infection. The ability to quickly test and diagnose people with COVID-19 is necessary to slow the spread of SARS-CoV-2, benefiting everyone. When a person is accurately diagnosed with COVID-19, they can isolate themselves immediately and minimize the chances of the virus being spread to others. Isolating those who test positive early in the infectious period, and initiating contact tracing immediately, could potentially decrease the rate of community transmission.

Using at-home testing also has the potential to increase lab capacity to do confirmatory RT-PCR diagnostic testing, as required, rather than using RT-PCR testing to monitor broad populations of asymptomatic people who want precautionary testing 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 helps curb the spread of the virus.

In Wales, people who are unable to work from home are being provided with 3 free rapid antigen tests per week to facilitate ongoing asymptomatic screening for SARS-CoV-2 infections.<sup>8</sup> More frequent testing will allow people to isolate more quickly when an infection is detected and help to curb spread.

## Availability in Canada

On April 23, 2021, Health Canada granted Interim Order market authorization for the Lucira Check-It COVID-19 Test Kit, the first at-home self-test for COVID-19 available in Canada.<sup>6</sup> The test was authorized for use by people with, or without, symptoms of COVID-19 and will be available for sale without a prescription.<sup>5</sup>

As of May 14, 2021, Health Canada was in the process of reviewing Abbott's Panbio COVID-19 antigen self-test, but market authorization had not yet been granted at the time this article was published.<sup>9</sup>

In the US, the Lucira Check-It COVID-19 Test Kit is also the only molecular testing kit available over-the-counter and has been authorized for use by individuals 14 years of age and older who take their own samples, and for children 2 to 13 years of age, with an adult obtaining the sample.<sup>5</sup> Other at-home testing options that have received Emergency Use Authorization from the FDA are antigen tests, which can be less sensitive than molecular tests.<sup>10</sup> These tests, including the Ellume COVID Home Test and the Abbott BinaxNOW coronavirus self-test kits, were to be available for sale at national pharmacy and grocery chains in the US beginning in late April 2021.<sup>10</sup>

## What Does It Cost?

The Lucira Check-it COVID-19 Test Kit will be available for online purchase from the manufacturer in Canada beginning in June 2021 and is expected to cost C\$75 for a single, one-time use kit, plus any applicable tax and shipping fees.<sup>5</sup>

In the US, the single-use Lucira Check-it COVID-19 Test Kit is available directly from the manufacturer for US\$55.<sup>11</sup> Abbott's BinaxNOW will offer 2 tests for US\$23.99 and the Ellume single-use COVID test kit will be available for \$38.99.<sup>10</sup>

In Canada, most tests currently used for the detection of SARS-CoV-2 are publicly funded and the costs associated with procurement and administration are not clearly reported. The total cost of administering RT-PCR tests would include the combined cost of testing equipment, testing supplies, and health care worker resources required to take the samples, ship the samples to the lab, and pay the salaries of lab workers to run the tests. The availability of at-home testing may represent a reduction in cost burden to the health care system but an increase in personal cost to the individual.

## Current Practice

Lab-based RT-PCR tests with high sensitivity remain the gold standard for the diagnosis of SARS-CoV-2 infection in Canada.<sup>2</sup> These tests are mainly administered at community testing centres or by rapid RT-PCR testing at the POC.<sup>2</sup> A positive result from either kind of test means the individual currently has COVID-19.<sup>2</sup> PCR tests are not recommended for people who are not showing symptoms of COVID-19 or who have not been identified as a close contact of someone diagnosed with COVID-19.<sup>2</sup>

Rapid antigen testing is not being frequently used in Canada. Despite the procurement of more than 41 million rapid tests, to date, 7.1 million have been deployed and fewer than 2 million of those tests have been used.<sup>12</sup> As well, to date, Prince Edward Island (13.6%) and Ontario (11.8%) show the largest percentages of use of their allocated rapid tests.<sup>12</sup> Some pilot projects involving asymptomatic workplace antigen testing are currently underway.<sup>13</sup>

At-home tests, while now authorized for use, were not yet available for individual sale in Canada at the time this article was published.

## What Is the Evidence?

The FDA determines the efficacy of these tests based on the positive percent agreement (PPA) and negative percent agreement (PNA). This is the amount of agreement between the new test and the established gold standard for the same indication. In this case, the at-home tests are compared with RT-PCR tests for the detection of SARS-CoV-2. A higher PPA or PNA means better accuracy. These values can differ depending on whether the tests are being used for people with, or without, symptoms of COVID-19. Health Canada has reported the sensitivity of authorized tests for SARS-CoV-2. Those values are available at this [website](#).<sup>6</sup>

**Table 1: Accuracy of At-Home Tests for SARS-CoV-2**

Test name	Type of test	Currently authorized in Canada	Prescription or over-the-counter	Positive percent agreement	Negative percent agreement
<b>Lucira Check-It COVID-19 Test Kit<sup>4,14</sup></b>	LAMP, unsupervised sample collection, screening	Yes	OTC	Symptomatic: 94% Asymptomatic: 90% Overall: 92%	Overall: 98%
<b>BinaxNOW COVID-19 Ag Card Home Test<sup>15,16</sup></b>	Antigen, unsupervised sample collection	No	Prescription	91.7% (95% CI, 73.0% to 98.9%)	100%
<b>BinaxNOW COVID-19 Antigen Self Test<sup>4,15,17</sup></b>	Antigen, serial screening, unsupervised sample collection	No	OTC	91.7% (95% CI, 73.0% to 98.9%)	100%
<b>BinaxNOW COVID-19 Ag Card 2 Home Test<sup>15,18</sup></b>	Antigen, serial screening, supervised sample collection	No	OTC	91.7% (95% CI, 73.0% to 98.9%)	100%
<b>Ellume COVID-19 Home Test<sup>15,19</sup></b>	Antigen, screening, unsupervised sample collection	No	OTC	Symptomatic: 96% Asymptomatic: 91%	Symptomatic: 100% Asymptomatic: 96%
<b>QuickVue SARS Antigen Test<sup>15,20</sup></b>	Antigen, unsupervised sample collection	No	Prescription	84.8%	99.1%

CI = confidence interval; LAMP = real-time loop-mediated amplification; OTC = over-the-counter; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

## Safety

No known safety issues have emerged with the use of tests for SARS-CoV-2. The main concern with testing done outside of a laboratory is the potential for human error. An improperly conducted test could provide a false-negative result — that is, a negative test result in a person who is positive for the virus.

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.<sup>2</sup> One of the ways this can happen is 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.<sup>2</sup> 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.<sup>2</sup>

A risk of providing people with more frequent results from tests with lower sensitivity is the potential for behaviour modification based on those results. Compliance with public health measures may be decreased due to a false sense of security in the receipt of a negative test result that may be incorrect.<sup>21</sup>

## Issues to Consider

While the availability of at-home testing can be considered a step in the right direction, access and affordability may be barriers to significant uptake in the community. The C\$75 out-of-pocket cost associated with the Lucira Test Kit will likely be a barrier for many people, particularly in populations that are the most at-risk of COVID-19 infection. Additionally, in the beginning, the tests will only be available for purchase online, which means access to the internet, a computer, and having a credit card will be required for purchasing these tests. Additionally, physical limitations may prevent some people from taking their own samples, therefore making at-home testing an inaccessible option even if it is financially affordable. Supporting equitable access to these types of tests could increase their impact on the trajectory of the pandemic in Canada.

It is important that the manufacturers' instructions for self-sampling are followed closely to ensure the most accurate test results. The results of any test are only as good as the sample that is put into it for analysis, so poor-quality self-sampling can potentially lead to poor-quality, or inaccurate, test results.<sup>3</sup>

At-home tests for COVID-19 are generally authorized for use by both people with and without symptoms. The accuracy of tests can vary depending on the stage of viral infection; testing too early or too late can provide inaccurate results. Neither antigen nor LAMP tests are as sensitive or specific as lab-based RT-PCR tests.<sup>3</sup> A positive result for someone with symptoms should be considered accurate and proper isolation should be followed. A positive result for someone who is not showing symptoms may be true or a false-positive and should be followed with a confirmatory RT-PCR test, when possible.<sup>3</sup> Similarly, a negative self-test result for a person who is showing symptoms of COVID-19 should also be confirmed by laboratory testing.<sup>3</sup> The FDA has designated a number of the available at-home antigen tests as screening, rather than diagnostic, tests — which means that any positive test should be confirmed with an RT-PCR test.<sup>15</sup>

## Related Developments

Tests to detect SARS-CoV-2 have also been developed that rely on at-home sample collection, where the individual collects their own sample and sends it back to a laboratory for further testing and analysis. These types of testing programs are currently in place in Canada.<sup>22</sup> Switch Health provides self-collection testing kits that must be used while participating in a video call with a nurse who verifies that the correct sampling methods have been followed.<sup>22</sup> Once the sample is collected, it is picked up by a courier and sent to a lab for processing. Results are typically available through a secure patient portal, within 2 to 4 days.<sup>22</sup> Currently, these testing kits are being used by international travellers after they have arrived in Canada. They are required to complete molecular COVID-19 testing as part of their entry requirements. The test is completed upon arrival in Canada and travellers are sent home with a self-sampling test kit to complete on day 8 of their 14-day quarantine period.<sup>22</sup>

In the US, the FDA recently granted Emergency Use Authorization to the Symbiotica COVID-19 Self-Collected Antibody Test System.<sup>23</sup> This is the first antibody test authorized for use with home-collected, dried blood spot samples, which are sent to a lab for analysis. Antibody tests look for antibodies in the blood and determine whether antibodies to SARS-CoV-2 are present.<sup>23</sup> The presence of these antibodies indicates either a prior SARS-CoV-2 infection or successful immunization.

Other manufacturers of LAMP and antigen tests are working toward creating at-home testing options for COVID-19.<sup>3</sup>

## Looking Ahead

At-home testing may become more common as more activities, events, and travel are allowed during the remainder of the COVID-19 pandemic and beyond. In April 2021, the San Francisco-based Golden State Warriors professional basketball team partnered with Lucira Health to provide at-home COVID-19 test kits to game attendees as part of the ticket price.<sup>24</sup> The arena was able to reopen at 35% capacity per local public health guidelines. Attendees were required to provide either proof of full vaccination against SARS-CoV-2 or display a negative Lucira Check-It test result obtained within 48 hours of the game.<sup>24</sup> People who were fully vaccinated but seated within 30 feet of the basketball court were also required to produce a negative test result prior to the game.<sup>24</sup>

Take-home COVID testing is being piloted in some Canadian schools. Prior to the temporary suspension of in-class learning, saliva self-sampling kits were being sent home with children in some parts of Toronto.<sup>25</sup> These are not rapid or at-home testing kits but allow the samples to be gathered at home and dropped back at the school prior to processing in a lab. This type of sampling may remove some of the barriers to access like parents getting time off from work and the availability of transportation to get to community testing facilities.<sup>25</sup> In British Columbia, saline gargle self-sample kits are being provided to children who feel unwell at school.<sup>26</sup> The sample can be collected at home and dropped off at any LifeLabs location for processing.

Testing is an important and evolving factor in the management of the pandemic. For testing to be an effective part of public health strategy, it must be easily and equitably available to all who need it. This would include both location of, and access to, testing locations and ensuring enough tests, equipment, and people have been secured to provide an adequate number of tests relative to demand. The COVID-19 pandemic has magnified existing direct and indirect societal inequities. Public health measures like quarantine, physical distancing, and testing do not have the same impacts on everyone. These factors are important when assessing interventions related to COVID-19.

Despite the success of ongoing vaccination campaigns around the world, testing for SARS-CoV-2 and the diagnosis of COVID-19 will continue to remain an important part of public health measures.<sup>27</sup>



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