

CADTH Health Technology Review

Considerations for the use of COVID-19 Rapid Tests

Authors: Sarah Berglas, Tamara Rader, Quenby Mahood

Acknowledgements: CADTH would like to thank all contributors for their time and perspectives, including:

Michaela Knot and Mahadeo Sukhai, CNIB Foundation

Jennifer McDonnell and Julie Kelndorfer, Multiple Sclerosis Society of Canada

Lisa Salapatek, Ontario Caregiver Organization

Carrie Costello, Children's Hospital Research Institute of Manitoba

Linda Wilhelm and Laurie Proulx, Canadian Arthritis Patient Alliance

Mary Reeves, who lives with osteoarthritis and vision impairment in New Brunswick

Disclaimer: The information in this document is intended to help Canadian health care decision-makers, health care professionals, health systems leaders, and policy-makers make well-informed decisions and thereby improve the quality of health care services. While patients and others may access this document, the document is made available for informational purposes only and no representations or warranties are made with respect to its fitness for any particular purpose. The information in this document should not be used as a substitute for professional medical advice or as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision-making process. The Canadian Agency for Drugs and Technologies in Health (CADTH) does not endorse any information, drugs, therapies, treatments, products, processes, or services.

While care has been taken to ensure that the information prepared by CADTH in this document is accurate, complete, and up to date as at the applicable date the material was first published by CADTH, CADTH does not make any guarantees to that effect. CADTH does not guarantee and is not responsible for the quality, currency, propriety, accuracy, or reasonableness of any statements, information, or conclusions contained in any third-party materials used in preparing this document. The views and opinions of third parties published in this document do not necessarily state or reflect those of CADTH.

CADTH is not responsible for any errors, omissions, injury, loss, or damage arising from or relating to the use (or misuse) of any information, statements, or conclusions contained in or implied by the contents of this document or any of the source materials.

This document may contain links to third-party websites. CADTH does not have control over the content of such sites. Use of third-party sites is governed by the third-party website owners' own terms and conditions set out for such sites. CADTH does not make any guarantee with respect to any information contained on such third-party sites and CADTH is not responsible for any injury, loss, or damage suffered as a result of using such third-party sites. CADTH has no responsibility for the collection, use, and disclosure of personal information by third-party sites.

Subject to the aforementioned limitations, the views expressed herein are those of CADTH and do not necessarily represent the views of Canada's federal, provincial, or territorial governments or any third-party supplier of information.

This document is prepared and intended for use in the context of the Canadian health care system. The use of this document outside of Canada is done so at the user's own risk.

This disclaimer and any questions or matters of any nature arising from or relating to the content or use (or misuse) of this document will be governed by and interpreted in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein, and all proceedings shall be subject to the exclusive jurisdiction of the courts of the Province of Ontario, Canada.

The copyright and other intellectual property rights in this document are owned by CADTH and its licensors. These rights are protected by the Canadian

Context

Testing is an important and evolving factor in the management of the COVID-19 pandemic. Testing – regardless of setting or test type - provides a snapshot of a person’s current infection status by detecting the presence of SARS-CoV-2 proteins (rapid antigen tests) or nucleic acids (molecular tests).¹ COVID-19 rapid tests may be used to help quickly identify and isolate people who have COVID-19. This includes people who don't have any symptoms.¹ In some cases, serial testing (multiple tests over several days) may be done to increase the accuracy of the test.¹ The use of rapid COVID testing has the potential to benefit a wide range of people. The ability to use these tests 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. Rapid tests can provide accurate results in less than 30 minutes compared with 1 or more days for laboratory testing results. For testing to be an effective part of public health strategy, it must be easily and equitably available to all who need it.²

Most rapid tests procured and distributed by governments for use by the public have been rapid antigen tests. Some of the tests were authorized for point of care use (sample collection and test use by or trained by a healthcare professional) and distributed for self-testing while others were authorized for both point of care and self-test use. Self-tests procured by governments may not be the same as those available for purchase by individuals. For additional information on tests that have been authorized for use in Canada, Health Canada publishes a list of Authorized COVID-19 Medical Devices.³

In December 2021, free rapid tests were being distributed in New Brunswick, Nova Scotia, Saskatchewan and Ontario at pop-up testing sites, libraries, health centres and stores. Rapid test kits were offered to students and children in Alberta, Ontario, Saskatchewan, Nova Scotia, Prince Edward Island, and Quebec. Residents of Quebec⁴ were also able to collect self tests from pharmacies. In B.C., non-profits, charities, and Indigenous community organizations could access free tests through the Canadian Red Cross.⁵ People and families can also directly purchase tests when stock is available. By June 2022, Health Canada had authorized 18 different self-testing devices.³

Objectives

The key objectives of this Environmental Scan are:

1. Explore the accessibility of COVID-19 testing devices, in the context of different community needs, for example, parents testing young children, those with vision loss, or limited manual dexterity.
2. Identify examples of urgent public health needs related to self-testing for these populations.

Purpose

The purpose of this Environmental Scan is to present health care stakeholders in Canada with an overview of community views about COVID-19 testing devices, a description of some of the published literature, and a summary of some considerations related to the use of COVID-19 tests by different groups. This report is not a systematic review and does not involve critical appraisal or include a detailed summary of study findings. Rather, this report presents an overview of the technology and considerations on the use of COVID-19 rapid tests. It is not intended to provide recommendations.

This Environmental Scan does not include an assessment of the clinical or cost-effectiveness of the technology area; thus, conclusions or recommendations about the value of the technology or place in therapy are outside of the scope of this report. Additionally, this Environmental Scan does not endorse one form of testing device over others.

Methods

Approach

CADTH involves patient groups, families, and community to improve the quality and relevance of our work, ensuring that those affected by the health technology assessments have an opportunity to contribute to them. CADTH has adopted a Framework for Patient Engagement in Health Technology Assessment⁶. The framework includes standards for patient involvement in individual assessments and is used to support and guide our activities involving community collaborators in this report.

Consultations

Targeted consultations were sought with community organizations to identify barriers or accessibility concerns with use of COVID-19 rapid tests. Individuals and organizations contacted for this report were identified by CADTH's patient engagement team and network of liaison officers situated across Canada. The Multiple Sclerosis Society of Canada sought experiences from the information, support, and referral service (MS Navigator Program) and the CNIB Foundation explored accessibility of specific Health Canada approved rapid tests. The Ontario Caregivers Organization and Children's Hospital Research Institute of Manitoba reached out to their own membership, inviting comments.

Additionally, websites of organizations serving older adults (Canadian Seniors Association, Canadian Association of Retired Person), parents (Toronto District School Board), new immigrants (CultureLink), underserved communities (Canadian Red Cross, Black Health Alliance, Black Creek Community Health Centre, Vaughan Community Health Centre, Saskatoon Public Library, and Halifax Public Library), and Indigenous communities (First Nations Health Authority) were searched for information on rapid antigen tests or at home tests. CADTH's Implementation Support and Knowledge Mobilization team also spoke with senior management in Nova Scotia long-term care, Manitoba public health and primary care, and Newfoundland and Labrador long-term care, public health, and education, on the distribution and use of self-testing in their communities. Information from provincial ministry of health websites, published studies on barriers to use of COVID-19 rapid antigen testing, national and local media, and private suppliers of tests, was used for context.

Synthesis

Notes obtained through telephone and video consultations were hand-written. Key points from notes and comments obtained through email consultation were grouped into themes under the objectives of this Environmental Scan.

Findings

Self-testing for COVID-19 infection is quick and convenient. For those with symptoms, it supports rapid diagnosis without the risk of infecting others to travel for testing. For those without symptoms, it can provide information and reassurance prior to, or following, group interactions. It can be used frequently for families with young children who are not yet eligible for vaccination or by those at increased risk to infection. For testing to be an effective part of public health strategy, it must be easily and equitably accessible to all who need it.

The consultations identified that factors related to location, physical mobility, vision, language, culture, clarity in instructions, age, willingness to test, availability of tests, and cost can affect the ability to use rapid tests for COVID-19. Read on for details on each of the factors identified during consultations

Clean and safe surroundings

In addition to a rapid test, a clean surface, clean hands, privacy to do a nose swab, an uninterrupted 20 to 30 minutes, and a timer, are required to complete a self-test. Tests should not be stored in vehicles, in mail boxes or lockers, or in rooms, where the temperature may go below 2C or above 30C. ⁷ As such, those who are inadequately housed face barriers to self-testing.

Manual dexterity

Separate packages for the cassette, assay buffer, and swabs need to be torn open, and the cap to the assay buffer opened. Those with limited hand movement and/or strength (for example with arthritis) have physical difficulty manipulating the packing and squeezing the assay. Fine motor control is needed to guide the swab into the nose, transfer swab to assay, and to control the drops into the cassette well. Those with hand tremors (for example with multiple sclerosis or Parkinson disease) may be concerned about spilling the liquid and wasting a test, especially when a person has a limited supply of tests.

Vision

Those with sight loss are unable to independently read the printed instructions, place components together, add the drops into the cassette well, or verify the results of rapid antigen tests. Providing instructions in braille, large print, digital or audio formats can begin to address this issue. ⁸ In discussions with CNIB Foundation staff, we learnt that some tests have instructions that can be read via a screen reader, but some images lack descriptive text and use of tables in some instructions scramble the order of steps, when using a screen reader. Even with support for instructions, barriers remain in counting the drops into the cassette well and reading the result as expressed by colour based (and often faint) bands. A test with a tactile or audio result, or with digital app to view and announce the result, could be useful.

In the UK, (not in Canada) Be My Eyes Specialized Help ⁹ connects a person with vision loss with a volunteer with public health training to guide the person through the steps of doing a swab using a mobile device or computer with a camera. As each test is different, the volunteer needs experience with a range of tests. Willingness to have a volunteer also learn the test result is a privacy consideration.

Understanding of instructions

More recently, self-testing packages include written instructions in English and French. Instructions are detailed, technical, and require a high level of literacy to understand. Many test manufacturers have produced procedure cards, with diagrams and simplified instructions, included within the test pack, or simple instructions and short videos available on their website. Videos and plain language instructions tend to only be available in English. The Government of Ontario has produced fact sheets on why to test, when to test, and what to do with the result, to support rapid testing, in 25 different languages. ¹⁰

In the effort to widely distribute rapid tests, health centres, schools, churches, and community organizations have divided larger boxes of tests into smaller packages to share the limited supply with more people. Boxes of 25 were divided into packages of five or two. Photocopies of simple instructions were typically included; but not consistently. As described by one Ontario parent, "I have managed to receive the rapid tests through the kids' schools, but they have often been lacking the instructions for how to use it. We end up googling them, but I can imagine if tests are being dismantled (which they have been due to short supply) then it can be hard to figure it out how to use them. I consider my digital health literacy as pretty high."

Culturally appropriate support:

The First Nations Health Authority provides guidance on lateral kindness and COVID-19 testing, in addition to videos and written resources by First Nations health providers on using rapid tests available to Indigenous communities.¹¹

Community health centres have shared links to resources on why test and what to do if testing positive, on their own websites and social media channels. For example, to address hesitancy and a lack of trust, especially among marginalized populations, Black Creek Community Health Centre in Toronto, hired members of the community to conduct daily outreach in the community, distributed rapid tests in community, and provided resources to support rapid testing.¹²

Willing to nose swab

The idea that a nasal swab is painful was a predominant perceived barrier to COVID-19 testing in a 2020 survey of 1,288 individuals, recruited from a volunteer participant registry in Arkansas, USA.¹³ The mucous membrane lining the nose has many nerve endings. Insertion of the swab can result in discomfort, sneezing, teary eyes, coughing, gagging, or pain. Discomfort, or fear of discomfort and pain, is compounded if there is uncertainty in how far to insert the swab.

For parents or family caregivers swabbing another person's nose, it can be hard to determine how far the swab is in the nose and to keep the swab steady during the swirl. As described by one Manitoba parent, as compared to a swab for a PCR test, "with antigen tests the time period needed to try and get 5 good swirls in each nostril is much more difficult and I am always worried about going too far or not far enough and how to really count swirls around the nose with someone who is fighting and keeps pulling their head one way and then another is a challenge.

For older and/or neurotypical children, family caregivers may be able to use reasoning to encourage the child to swab themselves or allow themselves to be swabbed. The IWK Health Centre created a resource to support use of Covid-19 rapid tests in children and youth. It includes practical advice and language suggestions, such as when swabbing "it's like painting the inside of your nose," and advice on depth of insertion.¹⁴

Clarity on where to swab

Ontario Health¹⁵ suggests that in addition to the collection method option as described in the test kit insert, users may choose to perform combined oral and nasal sampling as it may increase test sensitivity. Six Canadian provinces have recommended dual throat and nose swabbing when performing a self test in response to the emergence of the Omicron variant. Findings from three pre-print, non-peer reviewed publications¹⁶ indicate that using combined nasal plus throat, instead of nasal samples alone, resulted in greater detection rates without having an impact on true negative rates. Health care providers, pharmacists, and media have also suggested this approach. There is uncertainty if this is appropriate for all test, or for which rapid tests, and how this technique impacts accuracy of results.

Safe disposal

Instructions on some tests indicate disposal according to the appropriate biohazard waste disposal protocol. An example of this is the rapid antigen test Rapid Response (BTNX) distributed by the Ottawa Carleton District School Board in December 2021 for community use. However, local authorities in some regions, including Ottawa,¹⁷ have directed households to dispose of self-tests in a plastic bag within their regular garbage collection. Batteries used in molecular test, at home, also need safe disposal.

Trust in results

A repeated theme was mistrust in the accuracy of the results, especially a negative test result. We heard this concern from individuals, healthcare providers, patient organizations, and caregiver organizations. A 2021 German study of 4,026 participants exploring drivers and barriers of people's willingness to use rapid tests: gaps in understanding of the results; and the psychological and behavioral consequences of positive and negative results, sheds some light. Over a quarter of participants expressed doubts on the validity of the tests, with participants overestimating the number of test results that would turn out positive.¹⁸

Caregivers also expressed concern, especially when caring for vulnerable individuals and discerning whether to seek medical care, if the negative test was reliable in the presence of symptoms. If tests were easily available in the community, families would repeat tests over several days or seek a test from a different manufacturer, if symptoms continued. We also heard that having test kits at home can promote anxiety and over testing. Additional guidance on appropriate use of rapid testing, for different circumstances (symptomatic, asymptomatic, improving, or deteriorating symptoms, a positive case in a family all with negative tests) would be appreciated to assure appropriate and effective use of a limited resource.

Children and toddlers

Families are encouraged to test young children at home, to make decisions on attendance at daycare or school.^{19,20} Some rapid tests are indicated for children 5 years and older, others for 3 years and older; and others 2 years and older. Tests indicated for use in toddlers may not be available or easily accessible in all communities. Parents may feel uneasy or be unwilling to take on the responsibility of doing a nose swab with a crying or squirming child.

Older adults

Statistics Canada found that older adults and those without a child at home were less likely to use a rapid antigen test, in a February / March 2022 survey of 36,857 Canadians aged 15 and older.²¹ Statistics Canada caution against making inferences to the overall Canadian population, as the crowdsourced data was not collected using probability-based sampling. We did not find advice on COVID-19 testing on the websites of the Canadian Seniors Association, nor the Canadian Association of Retired Person. This may change as awareness and use grows of Paxlovid (nirmatrelvir; ritonavir) to treat mild to moderate COVID-19 in those at high risk for progression to severe illness. Older adults may be more likely to face vision and/or manual dexterity challenges than the general population and may need assistance in rapid testing. Personal care workers may not have the same access to test and training to use rapid tests, as staff in long term care settings.

Availability

All respondents spoke about early (and ongoing for some) challenges with availability of rapid tests. Most provinces restricted free distribution to specific communities and had limited tests to distribute. As described by one respondent: “People are usually grateful that they can get the test kits”, and others described gratitude and acceptance with what was available. However, a first-come, first served model of community distribution can reduce equity as it requires individuals to learn about where to access tests and to leave home to collect or purchase a test. An Ontario caregiver explained, “My parents only have rapid tests in their home because I provided for them. They did not know how to get any.”

Cost

When not available at free distribution centres, public were/are purchasing them from retail drug stores. Rapid Test and Trace,²² an online store for Health Canada approved tests, sells CovClear COVID-19 Rapid Antigen Test (2 Pack) for \$19.99 or Artron COVID-19 Rapid Antigen Test (5 Pack) for \$45.00, plus the cost of shipping. In Newfoundland, a pack of two rapid tests costs (approximately \$25) and is the equivalent to two hours of wages for a minimum wage worker.²³ The price of tests varies in different regions of the province. For example, a pharmacy in Happy Valley-Goose Bay, Labrador is selling a pack of 2 rapid tests for \$46.²³ Isolating with symptoms of COVID-19 in the absence of a self test, may result in lost education, lost work, and lost wages.²³

Limitations

Care has been taken to ensure the information is accurate and complete, but it should be noted that information about COVID-19 changes and varies across Canada.

To produce this report, CADTH used a modified approach to engage patient and community organizations to meet decision-making needs, including a short project timeline of four weeks. Stakeholders were invited to participate within a set time, that can sometimes make it difficult for people to participate fully, on terms that work for them (e.g., daytime videoconferences).

Inviting written comments via email or participating in video conferences were key tools used to obtain the views of a wide range of stakeholders in Canada. However, people need access to reliable technology, phone, and internet to collaborate with CADTH, which would exclude some voices. The distribution and diversity of the respondents may not be fully representative of all stakeholders.

The community was not involved in the topic selection or decisions about the scope of this report. People wanted to share concerns that were not part of the project scope, such as cost barriers or availability of tests, but the topic and question were identified prior to engagement.

Conclusions

Knowledge gained by rapid testing for SARS-CoV-2 can be empowering. Tests can rapidly provide information to individuals to determine need for isolation, to seek medical support, or to attend school, work, social events, or travel. A COVID-19 test can only be a self-test if everyone can use it without assistance. Inequity is increased if some in the community are unable to use a rapid test and cannot access the knowledge that the results of a rapid test offers. As part of the development, usability testing of devices including a broad diversity of human needs should be undertaken and reported. Each step of the testing process should be considered.

For broad community accessibility, rapid COVID-19 tests would have or be:

- Alternatives to nose swabbing, such as saliva, buccal, or breath testing.
- Suitable for use with infants, especially those too young for vaccination.
- Low cost, and/or available in single packages to distribute cost over time.
- Produced and distributed quickly and widely, during future waves of infection.
- Little packaging. Clearly indicate disposal by domestic garbage collection.
- Used and stored beyond temperature ranges of 2C to 30C for use in homes or vehicles without climate control.
- Single component test. No mixing of components by user required.
- Tactile or audio results, or digital app to view and announce the result.
- Instructions in braille, large print, digital or audio formats.
- Videos and plain language instructions in additional languages to English and French.

References

1. Government of Canada. Testing for COVID-19: when to get tested and testing results. 2022; <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/symptoms/testing/diagnosing.html#a2>. Accessed 2022 Jun 13.
2. Government of Canada. Information for patients: a guide to self-testing for COVID-19. 2022; <https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/testing-screening-contact-tracing/information-patients-guide-self-testing.html>. Accessed 2022 Jun 13.
3. Health Canada. Authorized medical devices for uses related to COVID-19: list of authorized testing devices. 2022; <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html>. Accessed 2022 Jun 13.
4. Quebec releases 10 million free rapid COVID tests. *Montreal Times*. 2021; <https://mtltimes.ca/covid-19/quebec-releases-10-million-free-rapid-covid-tests/#:~:text=The%20Quebec%20government%20will%20be%20distributing%20over%2010,have%20started%20climb%20rapidly%20over%20the%20past%20week>. Accessed 2022 June 17.
5. Should I get a rapid test before a holiday gathering? We answer this and your other COVID-19 questions. *CBC News*. 2021 Dec 17; <https://www.cbc.ca/news/ask-rapid-tests-holidays-omicron-variant-faq-1.6285520>. Accessed 2022 Jun 13.
6. CADTH framework for patient engagement in health technology assessment. Ottawa (ON): CADTH; 2022: <https://www.cadth.ca/cadth-framework-patient-engagement-health-technology-assessment>. Accessed 2022 June 17.
7. Government of Prince Edward Island. COVID-19 rapid antigen tests (self-test kits). 2022; <https://www.princeedwardisland.ca/en/information/health-and-wellness/covid-19-rapid-antigen-tests-self-test-kits>. Accessed 2022 Jun 13.
8. Houde C. Putting accessibility to the test. *Canadian National Institute for the Blind (CNIB) Foundation*. 2022; <https://www.cnib.ca/en/blog/putting-accessibility-test?region=on>. Accessed 2022 Jun 13.
9. Edwards L. Taking a COVID test completely blind [video]. 2021; https://www.youtube.com/watch?v=wuX1hYUy_YE. Accessed 2022 Jun 13.
10. Government of Ontario. Rapid testing for at-home use. 2022; <https://www.ontario.ca/page/rapid-testing-home-use>. Accessed 2022 Jun 13.
11. Lateral kindness and COVID-19 testing. West Vancouver (BC): First Nations Health Authority; [2022]; <https://www.fnha.ca/Documents/FNHA-Lateral-Kindness-and-COVID-19-Testing.pdf>. Accessed 2022 Jun 13.
12. Black Creek Community Health Centre. COVID-19 testing and updates. [2022]; <http://www.bcchc.com/about-us/covid-19-testing-and-updates/> Accessed 2022 Jun 13.
13. McElfish PA, Purvis R, James LP, Willis DE, Andersen JA. Perceived barriers to COVID-19 testing. *Int J Environ Res Public Health*. 2021;18(5):2278.
14. IWK Health, Nova Scotia Health Authority. COVID-19 rapid testing toolkit. [2022]; http://policy.nshealth.ca/Site_Published/covid19/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=93858. Accessed 2022 Jun 13.
15. COVID-19 rapid antigen tests: how to collect a sample. Toronto (ON): Ontario Health; Government of Ontario; 2022: <https://www.ontariohealth.ca/sites/ontariohealth/files/2022-02/COVID-19RapidAntigenTests-HowtoCollectaSample.pdf>. Accessed 2022 June 17.
16. Self-collection of nose and throat swab samples for SARS-CoV-2 antigen testing. Ottawa (ON): CADTH; 2022: <https://www.cadth.ca/self-collection-nose-and-throat-swab-samples-sars-cov-2-antigen-testing>. Accessed 2022 June 17.

17. Ottawa Public Health. How do I dispose of used rapid antigen test kits? *Rapid antigen testing for workplaces*. 2022; <https://www.ottawapublichealth.ca/en/public-health-topics/rapid-antigen-testing.aspx#How-do-I-dispose-of-used-rapid-antigen-test-kits>. Accessed 2022 June 17.
18. Betsch C, Sprengholz P, Siegers R, et al. Empirical evidence to understand the human factor for effective rapid testing against SARS-CoV-2. *Proc Natl Acad Sci U S A*. 2021;118(32).
19. Government of Manitoba. COVID-19 Rapid Antigen Tests (RATs): information for Manitobans. [2022]; https://manitoba.ca/covid19/testing/print_rat.html. Accessed 2022 Jun 13.
20. Government of Prince Edward Island. Licensed child care centre guidance. 2022; <https://www.princeedwardisland.ca/en/information/health-and-wellness/licensed-child-care-centre-guidance>. Accessed 2022 Jun 13.
21. Statistics Canada. Impacts of COVID-19 on Canadians: testing and vaccination, February 21 to March 13, 2022. *The Daily*. 2022 Apr 07. Accessed 2022 Jun 13.
22. Rapid Test & Trace. Get rapid testing for COVID-19: convenient virtual certifications for travel & work. 2022; <https://rapidtestandtrace.ca/>. Accessed 2022 June 17.
23. Roberts M, Roberts D. N.L. government says it has 'no control' over rapid test market. *CBC News*. 2022 Apr 29; <https://www.cbc.ca/news/canada/newfoundland-labrador/rapid-tests-cost-nl-1.6434367>. Accessed 2022 Jun 13.