

COVID-19 CADTH HORIZON SCAN

Rapid Point-of-Care Testing for COVID-19

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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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Key Messages

1. How are rapid point-of-care tests for COVID-19 currently being used, in Canada and internationally? (populations, settings, locations)
 - In Canada and other countries, rapid point-of-care COVID-19 tests are being piloted for use in asymptomatic populations in various settings, such as pop-up clinics, workplaces, long-term care, home care, rehabilitation facilities, and in schools and universities. In addition, rapid testing is being used or is being suggested for use in air travel and ports of entry, as well as in remote areas and settings where resources are limited.
 - Information on the use of rapid point-of-care tests across variable prevalence estimates was found, and some sources suggest use in high-prevalence settings where the positive predictive value is higher than in lower prevalence settings, whereas other sources suggest use in low-prevalence settings where negative predictive value is higher. The risk of a false-negative result and having a COVID-19 positive case misidentified continuing community exposure versus the risk of false positives and unnecessarily isolating a misidentified case needs consideration.
2. Does the use of rapid point-of-care tests for COVID-19 screening or diagnosis result in reduced COVID-19 transmission? If so, does this differ by population characteristics and/or settings?
 - No studies were identified that reported on the results of rapid point-of-care testing and transmission of COVID-19. The tests have been shown to fast-track triage, free up resources, and prevent bottlenecks in testing.
3. What information is available regarding “re-testing” (either with subsequent rapid point-of-care tests or with confirmatory reverse transcription polymerase chain reaction [RT-PCR]) for COVID-19?
 - If rapid point-of-care testing is considered for the asymptomatic population, repeat testing (resources recommend two to three days) has been suggested as an option. Confirmatory RT-PCR is also suggested.

Summary

Multiple rapid antigen tests and rapid molecular tests have been used in hospital settings, including:

- RT-LAMP¹
- RAPID Molecular Xpert Xpress test²
- QIAstat-Dx Respiratory SASR-CoV2 Panel³
- Nucleic acid amplification testing⁴
- Cepheid Xpert R Xpress SARS-CoV-2⁵
- Mobidiag Novodiag R COVID-19⁵
- FebriDX⁶
- Panbio COVID-19 Ag Rapid Test⁷⁻⁹
- VitaPCR RT-PCR¹⁰
- Coris COVID-19 Ag Respi-Strip.¹¹

Rapid antigen tests and rapid molecular tests have been recommended to only be used in patients with identified risk factors for COVID-19.^{12,13} In Canada, rapid antigen tests are being used and piloted to screen the asymptomatic general population in pop-up clinics and workplace settings, and for staff and residents in long-term and personal care homes (Table 2). Guidance from Ontario indicates rapid antigen testing should only be considered for asymptomatic individuals if they are high-risk or part of a screening pilot. In other countries, rapid antigen tests are being used to screen asymptomatic students in schools and universities, care homes and rehabilitation facilities, and outdoor cinema attendees (Table 2). US guidance reports use in long-term care facilities to increase visitation and are being considered for use in schools for children participating in sports and other events.

Rapid molecular tests are being used to screen asymptomatic patients, residents, and staff in hospitals, residents who wish to travel, businesses, and residents of rural and remote communities. Other countries are using it for air travellers, the National Basketball Association (NBA) bubble, and nursing homes (Table 3). RT–loop-mediated isothermal amplification has also been suggested to be useful in the field,¹⁴ at potential ports of entry,¹⁴ in low resource settings,¹⁵⁻¹⁷ in mobile community testing units,¹ and in care homes.¹ The majority of the studies that are testing the use of rapid tests in asymptomatic people do not report results such as detection of COVID-19 and transmission. Those with testing results report 0.2% to 1.0% positive cases.

No studies reported on the effect of rapid point-of-care (PoC) tests on transmission of COVID-19. The studies that were identified reported on performance characteristics of the test rather than outcomes of infection and transmission. They have been shown to fast-track triage, open up hospital resources, and prevent bottlenecks in testing.^{1-5,18-20}

An Alberta Health Services (AHS) rapid review²¹ cautioned the use of rapid test in low-prevalence populations and supported the use in high-prevalence settings. The AHS review reported support for use in remote communities and to help in areas with testing capacity issues. If a high sensitive test is not critical, Health Canada’s interim guidance states that rapid antigen tests can increase testing capacity, with repeat testing or other measures to balance the lower sensitivity. Scenarios where rapid antigen testing may be useful include remote workers, workers in high-risk settings, inmates who are new or have been out on visits, outbreaks, and remote settings.

A Cochrane review²² reported on positive predictive value (PPV; the probability that those testing positive have the condition) and negative predictive value (NPV; the probability that those testing negative do not have the condition) across prevalence estimates (5%, 10%, and 20% prevalence). Generally, the rapid antigen tests had higher PPV across prevalence estimates than rapid molecular tests, and NPV was higher across prevalence estimates for rapid molecular tests than rapid antigen tests. Some guidance recommended use in high-prevalence settings and not in low-prevalence settings. In the guidance documents that suggested use in low-prevalence settings, serial testing (every two to three days) was required.

Since a higher NPV indicates a negative test is less likely to be a false-negative, the risk of an infected person being misclassified as not infected and possibly transmitting the virus to others is low. On the other hand, a higher PPV would correctly identify those with the virus but may also cause some individuals to be misclassified as having the virus when they do not, leading to unnecessary quarantining.

The guidance documents identified were generally suggestions for use or interim guidance, considering the lack of evidence. Generally, the guidance documents suggest rapid antigen PoC tests be considered for use in situations where RT-PCR is not readily available or where rapid antigen PoC results will influence management of the situation. Serial testing (two to three days) is suggested in the guidance documents for asymptomatic individuals. Serial testing was suggested for those in health care (residents and staff), home care, long-term care, closed settings, and occupation settings with continued workplace transmission.

Conclusion

Although evidence is limited and results on outcomes such as transmission are not available, rapid PoC testing for COVID-19 in asymptomatic individuals seems to have value in some situations. Access to testing in areas that are remote or have resource constraints can be improved with rapid PoC tests. The burden on lab testing and triage can be improved by using rapid PoC testing. Long-term care facilities and home-care settings may also benefit from rapid testing. Caution is needed when using the tests in asymptomatic individuals considering the low sensitivity and the possibility of false positives, but may be suitable to rule out COVID-19 given the high NPV in low-prevalence settings. Serial testing (every two to three days) is suggested for rapid PoC tests and confirmatory RT-PCR for inconsistent findings.

Introduction

Rapid PoC testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19 disease, is a new option to improve the speed of testing and management of people with a positive test result. Rapid PoC tests include antigen and molecular tests. Antigen tests use lateral flow immunoassays to detect the presence of viral proteins and identify a current infection, while molecular tests detect viral genetic material.²²⁻²⁴ Some use devices similar to pregnancy tests that visually display a positive or negative result,²⁵⁻²⁸ while others require the use of bench top^{29,30} or hand held³¹ analyzers to display and interpret the results of the test. These tests 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.³² 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.³² While lab-based RT-PCR testing is the "gold standard" for diagnosis, it may take a day or longer to receive results, depending on testing volume.³³

Faster results mean people with positive tests can be isolated more quickly and contact tracing can begin in a shorter time span. More rapid testing could also lead to more frequent testing, allowing people with positive results to be identified in the earlier stages of infection.²⁴ 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 RT-PCR diagnostic testing. 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. Rapid tests have been developed and approved for use in people with symptoms, so their performance for screening of asymptomatic people in community or workplace settings is unclear.

To inform the use of rapid PoC tests for COVID-19 and their place in population testing strategies, it is important to understand how rapid tests are currently being used, in which settings and populations, and the impact of their use on transmission rates of COVID-19. For this Horizon Scan, CADTH conducted a brief scan and review of the evidence and guidance on the use of rapid tests in Canada and internationally.

Context

Currently, rapid PoC tests are approved for use in symptomatic people or those with suspected COVID-19. There is interest in knowing if these tests are appropriate for use as a screening test in the general, asymptomatic population in a variety of settings, and if so, the considerations for testing.

Questions

This Horizon Scan was informed by exploring the following questions:

1. How are rapid point-of-care tests for COVID-19 currently being used, in Canada and internationally?
 - In what populations and settings are rapid point-of-care tests for COVID-19 being used?

2. Does the use of rapid point-of-care tests for COVID-19 screening or diagnosis result in reduced COVID-19 transmission? If so, does this differ by population characteristics and/or settings?
3. What information is available regarding re-testing (either with subsequent rapid point-of-care tests or with confirmatory reverse transcriptase polymer chain reaction) for COVID-19?

Methods

Literature Search Methods

Limited literature searches were conducted by an information specialist on key resources including MEDLINE, the Cochrane Library, the University of York Centre for Reviews and Dissemination databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategies were comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were rapid antigen or nucleic acid amplification tests and COVID-19. No filters were applied to limit the retrieval by study type. The searches were limited to English language documents published between January 1, 2018 and December 1, 2020. Internet links were provided, where available.

An additional supplemental search was also conducted to identify high-level reviews and guidelines on rapid COVID-19 testing. Search filters were applied to limit study types in the supplemental search to health technology assessments, systematic reviews, meta-analyses, or network meta-analyses.

Selection Criteria and Summary Methods

Literature search results were screened by single reviewers. Reviewers selected publications according to the inclusion criteria presented in

Table 1 Screening was conducted with a focus on expediency and on records with greatest relevance; the intention was not to comprehensively retrieve every potentially relevant record. The database and focused internet search were supplemented by handsearching and publications that were nominated by collaborators (e.g., media reports).

Full texts of publications were not reviewed, but in some cases open-access full-text versions were non-systematically retrieved when abstracts were not available, or for additional details beyond what was available in titles and abstracts.

The most pertinent findings were summarized in tables and text.

Table 1: Selection Criteria

Populations	<ul style="list-style-type: none"> • Individuals undergoing screening for SARS-CoV-2 infection, including those who are asymptomatic (e.g., community screening at workplaces, schools, or long-term care facilities)^a • Individuals who are symptomatic with suspected or presumptive COVID-19 • Contacts of confirmed COVID-19 cases • Users of rapid PoC COVID-19 tests
Intervention	PoC rapid antigen tests or rapid molecular for SARS-CoV-2 used as a screening tool or as a diagnostic tool
Comparator	<ul style="list-style-type: none"> • A different rapid PoC COVID-19 test • No testing • RT-PCR test • No comparator or not applicable
Outcomes	<ul style="list-style-type: none"> • Users of rapid PoC tests for COVID-19 (e.g., occupational health and safety stewards, allied health professionals) • Populations and/or settings in which PoC tests for COVID-19 are being used (e.g., asymptomatic individuals in the workforce; schools) • Effectiveness and safety (e.g., rates of COVID-19 transmission) • Confirmatory testing strategies (e.g., re-testing with PoC test; RT-PCR test) • Recommendations regarding the use of rapid PoC tests for COVID-19
Setting	Any setting (e.g., schools, long-term care facilities, industry); within Canada or internationally
Publication type	Any publication type (e.g., systematic review, narrative review, guideline, position statement, controlled trial, observational study, grey literature, preprint, media report)

COVID-19 = coronavirus disease; PoC = point of care; RT-PCR = reverse transcriptase polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

^aMost PoC tests are approved for use in symptomatic individuals with suspected or presumptive COVID-19, and are not approved for use in asymptomatic individuals.

Results

How Are Rapid Point-of-Care Tests Being Used?

AHS published a rapid evidence review of rapid antigen tests COVID-19 tests on November 6, 2020.²¹ This report addressed the performance of rapid COVID-19 tests and the optimal strategies for deployment of rapid testing.

This report conducted a literature search of evidence published up until October 15, 2020, and includes five systematic reviews, one observational study, five validation studies, five commentaries, three guidelines determined to be from reputable sources, and two items from the grey literature. The body of evidence was critically appraised and assessed to be of low-moderate quality overall.

With regard to the optimal strategies for deployment of rapid testing in health care or community settings, the AHS report did not identify any peer-reviewed evidence regarding optimal strategies for rapid COVID-19 testing, or any evidence that these rapid antigen tests for COVID-19 have been implemented or evaluated in a real-world context. The recommendations developed in the AHS report are based on expert commentary and guidelines.

AHS summarized guidance from WHO and interim guidance from Health Canada as follows:

- Rapid testing should be used:
 - to monitor high-risk situations (e.g., outbreak control, populations with high community prevalence)
 - in remote communities without standard testing
 - to supplement testing capacity for asymptomatic testing
 - as a screening tool for symptomatic individuals (followed by confirmatory RT-PCR).
- Rapid antigen testing should be used with caution in the following situations:
 - where the reduced sensitivity of these tests could result in missed cases (e.g., populations with low prevalence)
 - where treatment decisions depend on the result
 - where lower sensitivity can't be mitigated by repeated testing protocols.

Health Canada³⁴ reports that it is important to identify situations where rapid PoC antigen tests can be used effectively to increase access to testing.

- Proposed scenarios:
 - prospective testing of asymptomatic workers in high-risk settings (e.g., large processing plants, long-term care facilities)
 - repeated testing of inmates entering a correctional facility
 - outbreak situations
 - repeated testing of workers in remote work areas.

AHS summarized interim guidance from the US Centers for Disease Control, and Prevention (CDC), and information from the US Department of Health and Human Services (HHS) as follows:

- Rapid antigen tests should be used for screening in high-risk congregate settings where repeat testing may quickly identify SARS-CoV-2 positive people.
 - Repeated use of PoC tests in congregate settings (e.g., nursing homes) may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround.
- Rapid antigen test results should be considered presumptive.
- RT-PCR should be used to confirm screening when antigen test is inconsistent with clinical context.
- HHS has purchased 100 million antigen tests with plans to distribute them to nursing homes and hospice centres (to test staff one to two times weekly), historically Black Colleges and Universities, and Indian Health Service.
- HHS report references the FDA statement that PoC antigen tests can be used for asymptomatic individuals if more sensitive tests are not feasible or if turnaround times are prolonged.

The AHS committee report provides two recommendations regarding considerations for rapid testing platforms and the development of a strategy for the deployment of rapid testing, but no guidance regarding how these tests are currently being used. However, the committee was generally in agreement that rapid testing could potentially be useful in key community settings (e.g., schools, screening travellers) or congregate living settings.

Current Use of Rapid Antigen Tests

Rapid PoC antigen tests for COVID-19 are currently being used in Canada and internationally (question 1). They are being deployed both for asymptomatic general public screening and for symptomatic screening — with positive results being confirmed by RT-PCR testing. The majority are in the pilot program or early deployment phases and are not reporting results or outcomes related to screening. In Nova Scotia, where prevalence of COVID-19 is currently low, pop-up clinics using rapid antigen testing had a positive test rate of less than 0.4% as of November 30, 2020. It was unclear at the time of writing this report whether all of the results of confirmatory testing were available. In Slovakia,³⁵ more than 3.5 million tests resulted in a 1.06% positive test rating. It was unclear before the testing what the prevalence of COVID-19 was in the general population.

Table 2 summarizes the examples of rapid antigen testing programs that were identified for this report.

Current Use of Rapid Molecular Tests

Rapid molecular tests for COVID-19 are currently being used in pilot screening programs in Canada and internationally (question 1). Many have been recently implemented and no data are currently available on their success at reducing transmission.

Table 3 summarizes the examples of rapid PoC COVID-19 molecular testing programs that were identified for this report.

Summary of Guidance for the Use of Rapid Point-of-Care Tests

This report identified 18 guidance documents regarding rapid PoC tests. These guidance documents address our questions about population, setting, and re-testing (questions 1 and 3):

- 15 reports provided guidance specifically on rapid antigen tests^{34,36-48}
- one Canadian report provided guidance specifically on rapid molecular tests⁴⁹
- two reports provided guidance on rapid PoC tests in general (i.e., did not specify antigen or molecular tests).^{50,51}

Four of the guidance documents are meant to apply to Canada: one is for all of Canada,³⁴ two are specific to Ontario,^{36,37} and one is specific to Manitoba.⁴⁹ One global interim guidance report was prepared by WHO. Seven guidance documents are meant to apply to the US. Five guidance documents apply to Europe, and one is specific to Australia.

Two of the guidance documents (Government of Canada,³⁴ WHO³⁸) were previously summarized in the AHS rapid review,²¹ and a previous version of the Centers for Disease Control and Prevention (CDC) report³⁹ was also included in the AHS review.

The specific recommendations from these guidance documents are provided in Table 4 and summarized below. Due to the lack of evidence for rapid PoC tests, specifically in asymptomatic individuals or in specific settings, the guidance provided in these documents are suggestions for proposed use, or interim guidance based on the available evidence, and should be interpreted with caution. In general, rapid antigen PoC tests were considered for use in situations where RT-PCR was not readily available or where rapid antigen PoC results would influence management of the situation; however, in most situations, confirmation of the antigen PoC result by subsequent RT-PCR is encouraged. The need to

confirm the result of a rapid antigen PoC test by RT-PCR varied by clinical scenario (i.e., symptomatic versus asymptomatic), by result of the test (i.e., positive versus negative), and whether the result would influence management of the situation. Rapid antigen PoC tests were generally considered beneficial for supporting outbreak investigations. Similarly, guidance from one report suggests that rapid molecular PoC test may be used in symptomatic individuals from high-prevalence settings, in remote or isolated settings, or to support urgent decision-making.

In low-prevalence settings, the use of an antigen PoC test was discouraged for general screening purposes but may be considered for serial screening in some settings or when fast identification of positive cases influences management decisions. Antigen PoC tests were considered for some asymptomatic populations (e.g., contacts of confirmed cases, some workplaces) or situations (e.g., RT-PCR unavailable), and discouraged in other asymptomatic scenarios (e.g., one-time screening).

In health care facilities, antigen PoC tests were suggested for use in the serial screening of health care staff, screening patients before admission, and for symptomatic staff and patients. In long-term care facilities, antigen PoC tests were suggested for serial screening of residents and staff, screening residents and visitors before admission. In other congregate settings, antigen PoC tests were suggested for use in serial screening of staff or inmates in correctional facilities, symptomatic individuals, and prior to entry.

In remote or isolated settings, antigen PoC is proposed for use in serial testing of workers, and in outbreak investigations.

In pediatric settings, antigen PoC tests are considered for outbreak investigations, serial testing of workers in schools, children with known exposure to COVID-19, and suggested for extracurricular activities. A negative antigen PoC test result was not considered sufficient to allow kids to return to school.

The use of antigen PoC tests was advised against at airports and border entry points.

Guidance on Rapid Antigen Point-of-Care Tests

High-Prevalence Settings

Recommendations for the use of rapid antigen PoC tests:

- In November 2020, the European Commission recommended antigen PoC tests, regardless of symptoms.⁴⁷
- In November 2020, European Centre for Disease Prevention and Control (ECDC) suggests⁴⁶ rapid antigen PoC tests within five days of symptom onset.⁴⁶
- In November 2020, the Minnesota Department of Health, considered rapid antigen tests for symptomatic individuals.⁴³
- In September 2020, WHO suggested that rapid antigen PoC tests be used to monitor trends in communities with widespread transmission.³⁸

Recommendations against the use of rapid antigen PoC tests:

- In November 2020, ECDC suggested only RT-PCR should be used in high-risk settings with vulnerable populations.⁴⁶

Low-Prevalence Settings

Recommendations for the use of rapid antigen PoC tests:

- In November 2020, the European Commission suggested antigen PoC tests could be used where fast identification of positive cases supports management decisions.⁴⁷
- In November 2020, ECDC suggested antigen PoC tests may be used for serial testing (e.g., every two to three days) in some settings (e.g., health care).⁴⁶

Recommendations against the use of rapid antigen PoC tests:

- In October 2020, a statement from Australia recommended against rapid antigen tests.⁴⁵
- In November 2020, the US Association of State and Territorial Health Officials discouraged rapid antigen PoC tests.⁴⁰
- In September 2020, WHO recommended against rapid antigen PoC tests in areas with zero or only sporadic COVID-19 cases.³⁸

Asymptomatic

Recommendations for the use of rapid antigen PoC tests:

- In November 2020, the Ontario Ministry of Health and Long-Term Care considered the use of rapid antigen tests for asymptomatic individuals who:³⁶
 - are confirmed contacts of COVID-19 cases
 - are international students
 - work on farms
 - identify as Indigenous.
- In November 2020, the Ontario Ministry of Health and Long-Term Care considered the use of rapid antigen tests for asymptomatic workers at sites of rapid antigen workplace screening pilot.³⁶
 - In November 2020, the Ontario Ministry of Health announced it will offer a screening program for the use of rapid antigen tests in workplaces to test asymptomatic employees.³⁷
- In November 2020, the Minnesota Department of Health considered rapid antigen tests for asymptomatic individuals if RT-PCR was not available.⁴³
- In November 2020, the European Commission considered the use of antigen PoC tests for targeted population-wide screening.⁴⁷
- In September 2020, WHO suggested that rapid antigen PoC tests be used to test asymptomatic contacts of COVID-19 cases.³⁸

Recommendations against the use of rapid antigen PoC tests:

- In November 2020, the Minnesota Department of Health advised against rapid antigen tests for asymptomatic individuals if there is a low probability of a positive result, or when a positive result would not lead to changes in COVID-19 management.⁴³
- In November 2020, the US Association of State and Territorial Health Officials discouraged rapid antigen PoC tests for one-time screening.⁴⁰
- In September 2020, WHO recommended against rapid antigen PoC tests for asymptomatic individuals (who are not contacts with a confirmed case).³⁸

Health Care Facilities

Recommendations for the use of rapid antigen PoC tests:

- In November 2020, England recommended the use of rapid lateral flow antigen testing for regular screening of asymptomatic National Health Service staff (every three to four days), with confirmation of positive tests by RT-PCR.⁴⁸
- In November 2020, the European Commission considered the use of antigen PoC tests at admission.⁴⁷
- In November 2020, the European Commission considered recurring testing by antigen PoC tests of health care staff (e.g., every two to three days).⁴⁷
- In November 2020, ECDC suggested⁴⁶ rapid antigen PoC tests within five days of symptom onset in symptomatic patients and staff⁴⁶ before admission.

Long-Term Care Facilities or Other Social-Care Facilities

Recommendations for the use of rapid antigen PoC tests:

- In November 2020, the Ontario Ministry of Health and Long-Term Care stated that the use of rapid antigen tests may be considered for asymptomatic workers or visitors.³⁶
- In November 2020, the European Commission considered the use of antigen PoC tests at admission.⁴⁷
- In November 2020, the European Commission considered employing recurring antigen PoC tests of staff (e.g., every two to three days).
- In November 2020, ECDC suggested⁴⁶ rapid antigen PoC tests within five days of symptom onset in symptomatic residents and staff⁴⁶ before admission.
- In November 2020, the Minnesota Department of Health considered rapid antigen tests for symptomatic individuals.⁴³
- In November 2020, the Minnesota Department of Health considered rapid antigen tests for serial testing of asymptomatic individuals.⁴³
- In November 2020, the US Association of State and Territorial Health Officials reported that some facilities are using rapid antigen PoC tests to screen visitors.⁴⁰
- In October 2020, the US CDC considered rapid antigen tests in nursing homes under three circumstances:⁴¹
 - symptomatic residents and staff
 - asymptomatic residents and staff as part of an outbreak investigation
 - serial testing of asymptomatic staff.

Congregate Settings or Closed Facilities

Recommendations for the use of rapid antigen PoC tests:

- In December 2020, the US CDC recommended rapid antigen tests for screening in high-risk congregate settings where rapid results could inform management.³⁹
- In November 2020, the Ontario Ministry of Health and Long-Term Care considered the use of rapid antigen tests for asymptomatic residents or workers.³⁶
- In November 2020, the European Commission considered recurring testing by antigen PoC tests of staff (e.g., every two to three days).⁴⁷

- In November 2020, ECDC suggested⁴⁶ rapid antigen PoC tests within five days of symptom onset.⁴⁶
- In October 2020, the Government of Canada proposed the use of rapid antigen tests for workers in high-risk settings before entry.³⁴
- In October 2020, the Government of Canada proposed the use of rapid antigen tests serial testing of inmates in correctional facilities.³⁴
- In September 2020, WHO suggested that rapid antigen PoC tests be used in outbreak situations in institutions and semi-closed communities where RT-PCR is not immediately available and to support outbreak investigations in these settings.³⁸

Schools or Pediatric Populations

Recommendations for the use of rapid antigen PoC tests:

- In November 2020, the US Association of State and Territorial Health Officials reported that some schools are using rapid antigen PoC tests for:⁴⁰
 - testing symptomatic children
 - testing children with known exposure to a COVID-19 case
 - serial testing of teachers and staff.
- In November 2020, the US Association of State and Territorial Health Officials considered rapid antigen PoC tests for screening kids participating in extracurricular activities.⁴⁰
- In September 2020, the American Academy of Pediatrics suggested that rapid antigen tests may be useful when screening a large number of children.
- In September 2020, WHO suggested that rapid antigen PoC tests be used to support outbreak investigations in schools.³⁸

Recommendations against the use of rapid antigen PoC tests:

- In September 2020, the American Academy of Pediatrics suggested a negative result from rapid antigen test was not sufficient for allowing kids to return to school.⁴⁴

Airports or Borders

Recommendations against the use of rapid antigen PoC tests:

- In September 2020, WHO recommended against rapid antigen PoC tests at airports or border screening points.³⁸

Remote or Isolated Settings

Recommendations for the use of rapid antigen PoC tests:

- In October 2020, the Government of Canada proposed the use of rapid antigen tests for serial testing of workers in remote areas.³⁴
- In September 2020, WHO suggested that rapid antigen PoC tests be used in outbreak situations in remote settings where RT-PCR is not immediately available.³⁸

Outbreak Investigations

Recommendations for the use of rapid antigen PoC tests:

- In November 2020, the Ontario Ministry of Health and Long-Term Care considered the use of rapid antigen tests for asymptomatic residents and staff at the sites of outbreaks.³⁶
- In November 2020, ECDC suggested⁴⁶ the use of rapid antigen PoC tests within five days of symptom onset⁴⁶
- In October 2020, the Government of Canada proposed the use of rapid antigen tests for outbreak investigations if presumptive results will inform decision-making.³⁴

Guidance on Rapid Molecular Point-of-Care Tests

From November 2020, interim guidance from the Province of Manitoba⁴⁹ suggested that rapid molecular tests only be used for symptomatic people within seven days of symptoms, and that rapid molecular tests should not be used for asymptomatic people. They recommended confirmation of all rapid molecular test results by RT-PCR.

Situations where rapid molecular tests may be appropriate include:

- high-prevalence settings
- support urgent decision-making in high-risk/high-consequence settings (e.g., shelters)
- remote and isolated areas.

Guidance on Non-Specific Rapid Point-of-Care Tests

Due to gaps in the evidence on rapid PoC test for SARS-CoV-2, in November 2020, the Infectious Disease Society of America⁵¹ made no recommendation for or against the use of rapid PoC tests for symptomatic people with suspected COVID-19.

In May 2020, guidance from Public Health England indicated that rapid PoC tests were not advised.⁵⁰

Rapid COVID Test Performance

Rapid PoC testing varies in performance and this section addresses the use across various prevalence settings and populations (question 1). Rapid PoC tests are meant to accurately determine the diagnosis of a patient suspected of having COVID-19; however, there are factors that affect the validity of these tests in determining the correct diagnosis. Overall, both antigen and molecular rapid point-of-care tests have been shown to compare well to the standard RT-PCR method of testing.^{7-10,22,52} Table 5 summarizes the identified studies that evaluated PPV and NPV of rapid PoC tests for COVID-19.

Many of the antigen and molecular rapid tests show high PPV and NPV values, reflecting a higher likelihood that a positive test is a true positive, and a higher likelihood that a negative test is a true negative, respectively. These values are affected by the prevalence of the virus where the tests are conducted, so may give some indications about test performance in different settings. For example, the Cochrane systematic review by Dinnes et al.²² included a meta-analysis of five rapid antigen test studies and 11 rapid molecular test studies, and estimated PPV and NPV at three different prevalence points (5%, 10%, and 20%) in a hypothetical cohort of 1,000 individuals. PPV for rapid antigen tests was generally higher across prevalence estimates than rapid molecular tests; NPV for rapid molecular tests was

generally higher across prevalence estimates than rapid antigen tests. The authors concluded that rapid PoC tests should replace lab-based RT-PCR if they are as accurate; however, given the methodological limitations in the test accuracy studies, they could not confirm the appropriateness of rapid tests for this purpose. The authors also concluded that based on the available evidence, rapid tests could only be used as a triage to RT-PCR (i.e., allowing for early self-isolation, quarantine, or treatment for those testing positive) in settings with a prevalence of at least 20%, given the relative risk of false-positive test results in settings with lower viral prevalence.

One study from Italy⁵² conducted an investigation of test performance in high and low-prevalence settings in the field. In this study, they evaluated the performance of the SD-Biosensor antigen test in a high-prevalence, diagnostic setting (185 symptomatic patients presenting to the emergency room), and in a low prevalence, screening setting (145 asymptomatic travellers returning from high-risk European countries). In the emergency room (ER), NPV and PPV were 73.6% and 100%, respectively (prevalence 104/145 by RT-PCR). For asymptomatic returning travellers, NPV and PPV were 100% and 97.9%, respectively (prevalence 5/145 by RT-PCR). These results suggest greater value of the test in a screening scenario in a low-prevalence setting than for diagnosis in a high-prevalence setting.

The validity of rapid PoC tests is associated with the onset of symptoms and evidence suggests that there is an optimal time frame in symptom progression to determine a more accurate diagnosis of COVID-19.⁹ One study⁹ found that the rapid antigen test (Panbio COVID-19 Ag Rapid Test, Abbott) performed best with higher viral loads, or within one week of symptom onset compared to later time points. Similarly, a second study⁵³ observed higher sensitivity when the rapid antigen test (Bioeasy Biotechnology Co.) was used within seven days of symptom onset or for individuals with high viral loads. Another study,⁵⁴ examined a rapid antigen test (Veritor) at different points from symptom onset. It found high agreement with the reference standard (Lyra PCR assay) (defined as 80% or higher, in alignment with FDA-EUA acceptance criteria for antigen testing) through six days from symptom onset, and further showed better performance at up to six days post-symptom onset in individuals presenting with two or more symptoms (compared to one symptom). A second antigen test (Sofia 2) was shown to have good agreement with Veritor at five days from symptom onset or less. Finally, similar results regarding better test performance with higher viral loads was observed by Scohy.¹¹

Although this is not a comprehensive assessment of all evidence, limited information was available regarding the optimal setting to determine accurate rapid PoC test results. While the studies summarized in Table 5 present the test performance features that would be affected by prevalence of SARS-CoV-2, most identified studies did not compare test performance in different settings or with varying prevalence. Additional information or assumptions about viral prevalence would be required to infer value of rapid test use in those settings. Additionally, many of the tests were completed in patients suspected of having COVID-19 or showing symptoms. Limited information was available regarding the accuracy of rapid PoC testing in asymptomatic individuals.

Limitations

- This Horizon Scan used abbreviated literature search and selection methods. It was not intended to be systematic, and information may have been missed.
- Full texts of selected publications were not always available; summaries were sometimes based on information presented in study abstracts.
- This Horizon Scan does not address the methodological quality of included publications as studies were not critically appraised. Results should be interpreted with caution.
- Studies were not identified that reported on outcomes such as the transmission of COVID-19 following rapid PoC testing in asymptomatic individuals or in low-prevalence settings.
- Although the use of rapid PoC tests to screen asymptomatic populations for COVID-19 has been recently implemented, evidence of its effectiveness to reduce transmission rates is not yet available.

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Appendix – Summary Tables

Table 2: Current Use of Rapid Antigen Tests for COVID-19

Country	Population and setting	Test or program	Date implemented	Outcomes
Canada ⁵⁵	Asymptomatic general public in a community setting.	<ul style="list-style-type: none"> • Pop-up clinics in Nova Scotia (Halifax, Wolfville, Dartmouth). • Rapid antigen test, confirmation of positives with PCR test. 	November 22, 2020	<ul style="list-style-type: none"> • 5,500 tested as of November 30, 2020 • 21 tests were positive • 2 confirmed positive according to one source (Maclean's magazine) • 2 false positives according to another source (Rapid test pilot program appears to be a success - HalifaxToday.ca)
Canada ⁵⁶	Long-term and personal care homes for rapid recurrent asymptomatic screening of staff and residents.	<ul style="list-style-type: none"> • “Nine care homes received Panbio rapid antigen tests from Abbott Rapid Diagnostics, a German product that was very recently approved for use in Canada, on November 27 to begin the first two-week deployment of the pilot.” (Moose Jaw, Regina, Saskatoon and Prince Albert) 	November 27, 2020	NA
Canada ⁵⁷	Used as a screening test, not a diagnostic test — unclear how the program will run.	<ul style="list-style-type: none"> • 87,000 PanBio antigen tests (Manitoba) 	TBD	NA
Canada ⁵⁸	“A screening program for long-term care homes and other workplaces” in Ontario. Cites that people who are symptomatic and close contacts are being tested.	1.2 million Panbio rapid antigen tests. “Panbio tests have been deployed to six long-term care operators for potential deployment in more than 30 long-term care homes, 27 retirement homes, eight hospitals, and 11 industry partners such as Ontario Power Generation, Air Canada, and Magna, with plans to expand further across province.”	Announced November 24, 2020	NA
Canada ⁵⁸	In Ontario, the “pilot program is an important opportunity to learn about the value of antigen	“Eight-week pilot of Panbio antigen testing for participating employers in the private, public and non-profit sectors,	Announced November 24, 2020	NA

Country	Population and setting	Test or program	Date implemented	Outcomes
	screening for asymptomatic workers in a range of workplace settings.”	prioritizing access for health care settings, essential frontline settings, and congregate settings.”		
Slovakia ³⁵	Mass population testing at testing sites.	<ul style="list-style-type: none"> • Rapid antigen test • Immediate 10-day quarantine for those who test positive 	November 2020	<ul style="list-style-type: none"> • 3,625,332 tests • 38,359 tests positive (1.06%)
Germany ⁵⁹	Federal government’s testing strategy introduced “point-of-care testing and to include people without symptoms or a known exposure to the virus into the testing strategy.” The directive requires reimbursement of antigen testing in priority settings “such as care homes, hospitals, doctors’ offices and rehabilitation facilities.”	<p>“rapid antigen testing to reduce the risk of infection with Sars-Cov-2 in care homes and to enable homes to stay open to visitors.”</p> <p>“To be able to test residents and others, and receive compensation, care homes are required to produce a ‘testing concept.’ This involves defining the groups to be tested; the frequency of testing; the processes involved in administering tests (including the procurement of the tests, training requirements, the need for personal protective equipment); and a definition of cases in which an antigen test should be replaced by a PCR test.”</p>	Mid-October 2020	NA
England ⁶⁰	“Target asymptomatic people who would otherwise not go through the standard booking process for tests at home or at a regional testing site.”	“NHS England plans to roll out a pilot in Bradford, West Yorkshire, which will see community pharmacies provide COVID-19 antigen tests to patients.”	TBD	NA
US ⁶¹	“Distribution of rapid tests to targeted entities HHS has also distributed tests to nursing homes, assisted living facilities, home health and hospice agencies, Historically Black Colleges and Universities (HBCUs), the Indian Health	“HHS is distributing 150 million rapid, Abbott BinaxNOW COVID-19 tests to expand strategic, evidence-based testing in the United States.”	September 28, 2020	NA

Country	Population and setting	Test or program	Date implemented	Outcomes
	Service, and States recovering from natural disasters.”			
US ⁶²	<p>Rapid Antigen tests deployed in more than 130 school districts in Massachusetts. To be used for students, teachers, and staff who are already showing symptoms of COVID-19 with the goal of being able to continue in-person education.</p> <p>Similar programs are or will be running in South Carolina (McMaster: COVID test kits will allow SC schools to reopen The State); Connecticut, where they may also do some random testing (State Announces Rapid COVID Testing Pilot Program for Schools - Connecticut Education Association (cea.org)); Texas (Houston-area school districts plan to participate in rapid COVID-19 testing program - ABC13 Houston), Idaho (First shipment of new COVID tests arrives, but details remain scarce (idahoednews.org)).</p>	More than 130 school districts in Massachusetts will receive BinaxNOW rapid antigen tests. Positive tests will be confirmed with PCR.	December 2020 for Massachusetts	NA
England ⁶³	Pilot project to test asymptomatic university students at De Montfort University.	“If you are one of the initial group of students selected, you will be contacted by your faculty. Over the following weeks, the testing will then be rolled out to include a wider population of DMU staff and students. Further details on testing will be available in due course.”	October 2020	NA

Country	Population and setting	Test or program	Date implemented	Outcomes
UK ⁶⁴	“Mass testing for COVID-19 using lateral flow tests.”	<p>“Several pilot studies of mass testing using lateral flow tests are underway to evaluate how well tests work in real-world settings. The way in which they will be evaluated is unclear.”</p> <p>This includes the NHS.⁴⁸</p>	November 23, 2020	“One test chosen for a national rollout of mass testing of asymptomatic people across Local Authorities: is good at identifying when people do not have the infection, but it could miss as many as half of people who are infected.”
England ⁶⁵	Asymptomatic outdoor cinema attendees in London, Birmingham and Ascot.	<p>“Before arrival, attendees would be given the option to purchase an integrated testing service using Medatest’s Spring rapid antigen test for £18 added to the cost of the event which would then be administered inside their car.</p> <p>Alongside this, they would also be given access to Synoptics’ Reactivate app, an innovative risk management solution which enables them to log their test and manage associated risk and infection spread.”</p>	December 4 to December 22, 2020	NA

DMU = De Montfort University; HHS = US Department of Health and Human Services; NA = not available; NHS = National Health Service; PCR = polymerase chain reaction; TBD = to be determined.

Table 3: Current Use of Rapid Molecular Tests for COVID-19

Country	Population and setting	Test or program	Date implemented	Outcomes
Canada ⁵⁶	Hospitals in Moose Jaw, Regina, Saskatoon, and Prince Albert will receive rapid PoC testing units to screen asymptomatic patients, residents and staff, with results available as quickly as 15 minutes	<ul style="list-style-type: none"> “Acute care facilities and mobile testing units piloting Abbott ID NOW tests, which are a polymerase chain reaction (PCR) test.” 	November 27, 2020	NA
Canada ⁵⁶	Residents of Saskatchewan “who need COVID-19 results to travel or businesses looking to implement rapid testing privately”	<ul style="list-style-type: none"> “Quantum Genetix will administer rapid tests on a user-pay basis, with results provided within 24-48 hours.” 	November 2020	NA
Canada ⁵⁷	Manitoba remote communities, “including Swan River, The Pas, Churchill, Thompson, Lynn Lake, Gillam and Flin Flon, where delays due to transportation issues, weather, or other factors could affect access to traditional testing and a timely public health response. These communities also have existing lab infrastructure, which is needed for rapid tests.”	<ul style="list-style-type: none"> Abbott ID NOW “Health care providers will follow provincial guidance on when a rapid test is appropriate or may be valuable as an early screening tool to identify possible outbreaks as quickly as possible. Rapid tests cannot replace traditional COVID-19 testing in all circumstances because they can only be used if a person has symptoms.” 	TBD	NA
Canada ⁵⁸	Ontario deployed new COVID-19 rapid tests that are “initially being used in hospitals and assessment centres in rural and remote communities, as well as to test people as part of early outbreak investigations in hotspot regions where there are high concentrations of COVID-19 cases.”	“Ontario has received approximately 98,000 ID NOW tests.”	Announced November 2020	NA
Canada ⁶⁶	“The Province of Manitoba is using a rapid COVID-19 test at Winnipeg’s new first responders testing site to help measure the accuracy of the test kits.”	Pilot project to test the accuracy of the Abbott ID Now rapid COVID-19 test kit	Announced December 2020	NA
US ⁶⁷	Airports deploying COVID-19 testing for passengers travelling to destinations (e.g., Hawaii) that require a negative test to travel include the following:	Rapid PCR testing for travel (Abbot ID now the most commonly cited). Many offer option of rapid PCR or rapid antigen testing (usually the cost is to the traveler; PCR usually more expensive)	October 2020 (dates not mentioned for all locations)	NA

Country	Population and setting	Test or program	Date implemented	Outcomes
	Newark NJ; Boston Logan International Airport, MA; San Francisco International Airport, California; Dallas Fort Worth Texas; Tampa, Florida	Travellers can be tested at the airport to be allowed to travel.		
US ⁶⁸	“Alaska, Florida, Louisiana, New Jersey, and Texas Receive First Shipments of Test Used in NBA Bubble.”	<p>“HHS Launches Pilot Program of Fast Molecular PoC Test for COVID-19.”</p> <p>“Portable, cartridge-based COVID-19 molecular test kits that provide rapid results. The pilot program will assess how to best integrate diagnostic technology developed by Cue Health, Inc., into strategies for disease surveillance and infection control in institutions such as nursing homes.”</p>	November 9 2020	NA
UK ⁶⁹	London Heathrow Airport launched rapid testing of travellers	Rapid LAMP test; results available within an hour with the hope of reducing the 14-day quarantine period	October 2020	NA
Italy ²	Hospital: Coronary Care Unit (patients admitted from ER or the field)	Rapid Molecular Xpert Xpress Test used in the CCU for patients requiring intervention who have not been properly triaged for COVID-19	December 2020	Time to result reported

CCU = critical care unit; ER = emergency room; HHS = US Department of Health and Human Services; NA = not available; TBD = to be determined.

Table 4: Guidance on the Use of Rapid Tests

Source	Country	Publication type	Recommendations and/or guidance
Antigen tests			
Government of Canada ³⁴ The use of rapid antigen tests October 7, 2020	Canada	Interim guidance	<p>Proposed use cases for rapid point-of-care antigen tests:</p> <ul style="list-style-type: none"> • Selected, symptomatic individual within 5 days of symptom onset (with confirmatory RT-PCR) • Serial testing of workers in remote areas (prevent introduction or minimize spread of COVID-19) • Prospective testing of workers in high-risk settings, including large processing plants (e.g., meat plants), long-term care facilities, offshore workers • Outbreak situations if faster presumptive results will help inform action • Serial testing of inmates in correctional facilities <p>RT-PCR should confirm all positive antigen tests until there is more evidence on these rapid antigen tests.</p> <p>Confirmation of negative antigen tests by RT-PCR depends on the clinical context of the test (e.g., symptomatic vs. asymptomatic, contact of confirmed COVID-19 case).</p> <p>If antigen tests are used in a monitoring approach, the ideal frequency is not yet defined.</p> <p>Summarized in the AHS rapid review.²¹</p>
Ontario provincial guidance ³⁶ Ontario Minister of Health and Long-Term Care November 20, 2020	Canada	Guidance document	<p>PoC testing:</p> <ul style="list-style-type: none"> • A positive result is considered preliminary and should also have a parallel sample for laboratory PCR test. • Rapid molecular testing is for diagnostic purposes only. • Rapid antigen testing is for screening purposes only. <p>“All rapid tests must be performed by a licensed specimen collection centre or a laboratory licensed under the Laboratory and Specimen Collection Centre Licensing Act.” (p. 4)</p>

Source	Country	Publication type	Recommendations and/or guidance
			<p>Guidance for asymptomatic individuals:</p> <p>“Only high-risk asymptomatic individuals or individuals from targeted testing groups or participating in a workplace rapid antigen screening pilot should be considered for testing as follows:” (p. 5)</p> <ul style="list-style-type: none"> • contacts of confirmed COVID-19 cases • workers and residents at sites of outbreaks • those part of a rapid antigen screening workplace pilot • targeted testing populations (with no known exposure or part of outbreak investigation) <ul style="list-style-type: none"> ○ workers or visitors of long-term care homes ○ workers of retirement homes ○ residents or workers in homeless shelters or other congregate settings ○ international students (after 14 day quarantine) ○ farm workers ○ individuals who identify as Indigenous • Patients with preliminary positive results from rapid antigen testing
<p>Ontario considerations for employer rapid antigen screening pilot³⁷</p> <p>Ontario Ministry of Health</p> <p>November 20, 2020</p>	<p>Canada</p>	<p>Information</p>	<ul style="list-style-type: none"> • Ontario will offer an 8-week rapid antigen screening pilot program for employers. • Aim: gain knowledge about the value of antigen screening for asymptomatic workers in a range of workplace settings, and increase COVID-19 support available to workplace settings. • For asymptomatic people only. • Only rapid tests currently available in Ontario and approved by Health Canada will be used. • Pilot will use the Abbott Panbio antigen screening test. • “All rapid tests must be performed by a licensed specimen collection centre or a laboratory licensed under the Laboratory and Specimen Collection Centre Licensing Act (LSCCLA) or by certain regulated health professionals that are specifically exempt from the licensing requirements of the LSCCLA.”

Source	Country	Publication type	Recommendations and/or guidance
			<ul style="list-style-type: none"> • Positive results will be considered preliminary and followed up by laboratory PCR. • Organizations need to have a systematic procedure in place to follow up on test results and plans in place to respond to positive COVID-19 diagnoses.
<p>Rapid antigen-detection of SARS-CoV-2³⁸</p> <p>WHO</p> <p>September 11, 2020</p>	Global	Interim guidance	<p>Rapid antigen tests with appropriate performance standards can be used in situations where RT-PCR is not available (or where turnaround times preclude clinical utility).</p> <p>Scenarios where rapid antigen could be used:</p> <ul style="list-style-type: none"> • respond to outbreaks in remote settings, institutions, and semi-closed communities where RT-PCR not immediately available (where possible, positive results should be confirmed with RT-PCR) • support outbreak investigations in closed or semi-closed situations (e.g., schools, prisons, dormitories, ships) (prioritize RT-PCR confirmation of negative results) • to monitor trends in communities, in particular essential worker and health care workers, or areas with widespread community transmission • early detection and isolation in areas with widespread community transmission (e.g., in health care facilities, care homes, prisons, front line staff, health care workers, contact tracing) • testing asymptomatic contacts of cases. <p>Situations where rapid antigen test should NOT be used</p> <ul style="list-style-type: none"> • asymptomatic individuals, unless they are a contact of a confirmed COVID-19 case • areas where there are zero or only sporadic cases • situations where management of the patient does not change based on results • airport or border screening at points of entry • screening before blood donation. <p>Summarized in the AHS rapid review.²¹</p>

Source	Country	Publication type	Recommendations and/or guidance
Using antigen tests ³⁹ CDC, US December 5, 2020	US	Interim Guidance	<p>Antigen tests can be use used for screening in high-risk congregate settings (e.g., student housing, transitional housing, shelters) in which repeat testing could quickly identify people with SARS-CoV-2 to inform prevention and control measures.</p> <p>Confirming rapid antigen test results with RT-PCR is situation dependent:</p> <ul style="list-style-type: none"> • symptomatic: negative results require confirmation, positive results do not • asymptomatic and close contact with COVID-19 case: positive results require confirmation, negative results do not • asymptomatic and no known exposure: positive results require confirmation, negative results do not. <p>An earlier version of this document was summarized in the AHS rapid review.²¹</p>
Association of State and Territorial Health Officials ⁴⁰ US November 2020	US	Considerations	<p>Symptomatic individuals:</p> <ul style="list-style-type: none"> • a positive PoC antigen test can confirm diagnosis • a negative PoC antigen test can be misleading, and person should isolate until PCR can be confirmed. <p>Asymptomatic individuals:</p> <ul style="list-style-type: none"> • discourages one-time asymptomatic screening (e.g., doctor's offices, airports, community settings) where test will not be repeated in a few days. <p>Communities with low transmission rates:</p> <ul style="list-style-type: none"> • consider recommending PCR tests rather than rapid PoC antigen tests. <p>Other considerations:</p> <ul style="list-style-type: none"> • confirmation of positive antigen tests with a PCR test is best practice where consequences of false-positive results could be harmful (e.g., moving nursing home patients to COVID-19 ward). <p>Long-term care settings:</p> <ul style="list-style-type: none"> • some long-term care facilities in the US are using rapid PoC antigen tests to increase visitation (tests provided by federal government)

Source	Country	Publication type	Recommendations and/or guidance
			<ul style="list-style-type: none"> • consider training on proper protocols for these tests to avoid result errors due to operator errors. <p>Schools/kids of school age:</p> <ul style="list-style-type: none"> • federal government is providing Abbott BINAX Now tests to states for suggested use in schools • several states are using antigen tests in schools for: <ul style="list-style-type: none"> ○ symptomatic children ○ children exposed to COVID-19 to reduce quarantine periods ○ screen teachers and staff through serial testing ○ considerations for PoC antigen tests should be made in extracurricular activities to screen kids participating in sports or other events.
<p>Considerations for use of SARS-CoV-2 antigen testing in nursing homes⁴¹</p> <p>CDC, US</p> <p>October 23, 2020</p>	<p>US</p>	<p>Considerations</p>	<p>Uses of antigen testing in nursing homes, 3 circumstances:</p> <ul style="list-style-type: none"> • Symptomatic residents and health care providers <ul style="list-style-type: none"> ○ Positive antigen test = isolate/exclude from work (no confirmatory test needed) ○ Negative antigen test = perform confirmatory RT-PCR immediately, isolate/exclude from work until RT-PCR results • Asymptomatic residents and health care providers as part of COVID-19 outbreak <ul style="list-style-type: none"> ○ PoC antigen testing every 3 to 7 days <ul style="list-style-type: none"> ▪ Positive = isolate/exclude from work (no confirmatory test needed) ▪ Negative = continue serial testing until no positives for 14 days • Asymptomatic health care providers in facilities without an outbreak <ul style="list-style-type: none"> ○ Serial PoC antigen testing based on local incidence of COVID-19 <ul style="list-style-type: none"> ▪ Positive = consider RT-PCR within 48 hours in low incidence areas ▪ Negative = continue serial testing <p>This document provided flowcharts to illustrate testing strategies.</p>

Source	Country	Publication type	Recommendations and/or guidance
<p>Potential for False-Positive results with antigen tests – letter to clinical laboratory staff and health care providers⁴²</p> <p>FDA, US</p> <p>November 3, 2020</p>	US	Letter to health care providers	<ul style="list-style-type: none"> FDA is aware of reports of false-positive results from antigen tests when used in nursing homes and other settings false positives are possible when users do not follow instructions for use for antigen tests. <p>Recommendations for clinical laboratory staff and health care providers who use antigen tests for the rapid detection of SARS-CoV-2:</p> <ul style="list-style-type: none"> follow manufacturer’s instructions for the rapid PoC antigen tests be aware that processing multiple specimens in batch more may introduce challenges for incubation timing minimize risk of cross-contamination <ul style="list-style-type: none"> consider the CDC’s guidance when using antigen tests in nursing homes and other settings remember that positive predictive value varies with disease prevalence when interpreting results from tests consider positive results in combination with clinical observations.
<p>Minnesota Department of Health⁴³</p> <p>Using PoC antigen tests in long-term care facilities</p> <p>November 11, 2020</p>	US	Guidance	<p>Consider antigen tests for symptomatic individuals, within 5 to 7 days of symptom onset for the following:</p> <ul style="list-style-type: none"> settings with high probably of a positive result situations where a positive result would change management in long-term care facilities with a COVID-19 outbreak high-prevalence areas with limited access to alternative testing. <p>Consider antigen tests for asymptomatic individuals in certain situations:</p> <ul style="list-style-type: none"> where timely RT-PCR is not available and there is no alternative to antigen tests serial screening in a closed long-term care setting (when RT-PCR is not available) and negative results will receive recurrent testing. <p>DO NOT consider antigen tests for non-serial testing of asymptomatic individuals where there is a low probability of a positive result, or where a positive result would not lead to changes in management.</p>

Source	Country	Publication type	Recommendations and/or guidance
			<p>Confirmation of antigen tests in long-term care facilities depends on presence of COVID-19 in the facility</p> <p>In facilities with COVID-19 cases in the last 14 days:</p> <ul style="list-style-type: none"> • symptomatic: confirmation by RT-PCR for negative tests, but not positive tests • asymptomatic: confirmation by RT-PCR for positive tests, and confirmation by repeat antigen test for negative results (in 3 to 7 days). <p>In facilities without COVID-19 cases in the last 14 days</p> <ul style="list-style-type: none"> • Symptomatic: confirmation by RT-PCR for negative and positive tests • asymptomatic: confirmation by RT-PCR for positive tests, and confirmation unnecessary if person will receive rapid antigen test on a recurring basis. <p>This document included flow charts to illustrate testing strategies.</p>
<p>COVID-19 Testing Guidance⁴⁴</p> <p>American Academy of Pediatrics, US</p> <p>September 30, 2020</p>	US	Guidance document	<p>Guidance for pediatric patients:</p> <ul style="list-style-type: none"> • Antigen tests may be useful when rapid results are required or when screening large numbers of individuals. • For return to school, a negative antigen test will often not suffice (confirmation of negative result using RT-PCR often required).
<p>Joint Statement on SARS-CoV-2 Rapid Antigen Tests. Public Health Laboratory Network – Communicable Diseases Network Australia ⁴⁵</p> <p>October 9, 2020</p>	Australia	Statement	<ul style="list-style-type: none"> • Resolution to many of the issues surrounding rapid PoC antigen tests is required prior to broader use of these tests (e.g., quality assurance) • there is a lack of published evidence on the performance of rapid antigen tests in real-life settings • discourages the use of rapid antigen tests where prevalence of COVID-19 is low • these tests may be useful in situations where a false-negative result is a reasonable risk (i.e., does not influence management of person) • further work is needed to inform their position on the use of rapid PoC antigen tests • “rapid antigen tests may have a role as a screening test for COVID-19 in certain contexts and settings, to be determined by jurisdictional public health authorities. This will be complementary to, and not a replacement for, RT-PCR testing” (p. 4)

Source	Country	Publication type	Recommendations and/or guidance
			<ul style="list-style-type: none"> “only a medical practitioner or suitably qualified person should perform or supervise the use of rapid antigen tests” (p. 4)
<p>Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK⁴⁶</p> <p>European Centers for Disease Prevention and Control (ECDC)</p> <p>November 19, 2020</p>	Europe	Technical report	<p>Use of rapid antigen tests may be beneficial, by public health objectives:</p> <ul style="list-style-type: none"> prompt management of patients with COVID-19 symptoms to control transmission (e.g., early detection, population-wide testing) triage upon admission at health care and social-care settings outbreak and cluster identification <p>High-prevalence settings:</p> <ul style="list-style-type: none"> rapid antigen tests can be used, with confirmatory RT-PCR for negative tests in high-risk settings with vulnerable populations only RT-PCR should be used <p>Low-prevalence settings:</p> <ul style="list-style-type: none"> negative antigen tests may require confirmatory RT-PCR recurring testing by rapid antigen tests every 2 to 3 days can be used to identify infectious cases, such as staff in health care settings <p>Symptomatic people:</p> <ul style="list-style-type: none"> if availability of RT-PCR is limited, rapid antigen tests can be used in settings where test positivity is high in some settings, rapid antigen tests should only be considered if sampling is within 5 days of symptom onset: <ul style="list-style-type: none"> high-prevalence situations, with cases presenting to health care confirmed outbreak investigations closed settings (e.g., prisons) triage symptomatic patients in health care and social-care setting prior to admission (e.g., patients, residents, staff) <p>Asymptomatic people:</p> <ul style="list-style-type: none"> rapid antigen tests recommended in settings where proportion of test positivity is $\geq 10\%$

Source	Country	Publication type	Recommendations and/or guidance
			<ul style="list-style-type: none"> • high-risk exposure contacts as part of contact tracing (negative tests followed by RT-PCR) • closed settings (e.g., long-term care) low-risk exposure contacts, rapid antigen tests can be used (negative tests followed by RT-PCR) • in high-risk prevalence settings, to detect individuals with high transmission potential in the community, rapid antigen tests can be used for targeted population-wide testing approach • rapid antigen tests can be used for screening and serial testing (every 2 to 3 days) of residents and staff in health care, home care, long-term care settings, closed settings (e.g., prisons), and occupational settings with ongoing community transmission. <p>Not recommended: Rapid antigen tests are not recommended for screening incoming travellers to prevent re-introduction in regions/countries that have achieved zero or very low levels.</p>
<p>European Commission⁴⁷ The use of rapid antigen tests November 18, 2020</p>	<p>Europe</p>	<p>Recommendations</p>	<p>Recommended settings for rapid antigen tests:</p> <ul style="list-style-type: none"> • Considered when availability of RT-PCR is temporarily limited in people with COVID-19 symptoms where the proportion of test positivity is high or very high • Recommended in settings where the proportion of test positivity is expected to be $\geq 10\%$ (e.g., outbreak investigations) regardless of symptoms • Considered at admission to health care facilities or social-care settings, and for triaging symptomatic patients or residents • Considered for targeted population-wide testing approach in order to detect individuals with high transmission potential in the community • Considered for recurring testing (e.g., every 2 to 3 days) of staff of health care, social-care, long-term care settings, closed facilities (e.g., prisons) or other front line staff in relevant sectors, in high-prevalence situations and/or limited RT-PCR testing • In low-prevalence settings, rapid antigen tests could be used in settings or situations where fast identification of positive cases is supporting management of outbreaks or regular monitoring of high-risk groups

Source	Country	Publication type	Recommendations and/or guidance
			<p>Considerations for use of rapid antigen tests:</p> <ul style="list-style-type: none"> Negative rapid antigen tests should be confirmed with RT-PCR or a repeated rapid antigen test (high-prevalence areas) Positive rapid antigen tests should be confirmed with RT-PCR or a repeated rapid antigen test (low-prevalence areas) “Rapid antigen testing should be conducted by trained health care personnel or trained operators where appropriate, and in accordance with manufacturer’s instructions. A critical point, often neglected, is the collection of the sample. Protocols for an efficient sample acquisition and handling should also be available.” (p. 6) “Rapid antigen tests should be used within five days after the onset of symptoms or within seven days after exposure to a confirmed COVID-19 case.” (p. 6) <p>Relevant evidence:</p> <ul style="list-style-type: none"> very limited data is available on the use of antigen tests in asymptomatic persons currently available antigen tests do not mention asymptomatic people in the manufacturer’s instructions.
<p>Novel coronavirus (COVID-19) standard operating procedure⁴⁸</p> <p>National Health Service (NHS), England</p> <p>November 16, 2020</p>	Europe	Guidance	<p>Procedure for regular testing of all asymptomatic NHS staff with lateral flow antigen testing.</p> <p>Objectives of regular testing:</p> <ul style="list-style-type: none"> support NHS in infection control risk reduction strategy reduce staff COVID-19 absenteeism support both COVID-19 and non-COVID-19 clinical pathways during the winter period/second wave <p>Guidance for testing in patient-facing asymptomatic staff:</p> <ul style="list-style-type: none"> staff should self-test twice a week (every three to four days). testing should be observed by a trained health care colleague, for the first time they administer the test. staff are advised to perform the test first thing in the morning, before starting work. If tested positive:

Source	Country	Publication type	Recommendations and/or guidance
			<ul style="list-style-type: none"> ○ follow organizational procedure to report the results to their supervisor and occupational health department. ○ urgent confirmatory RT-PCR testing is advised. Until the result of RT-PCR is available, the staff should self-isolate. ○ if the confirmatory test is negative, staff can rejoin duty immediately. ○ in case of a positive test, the staff member can restart home self-testing after 90 days from the positive test date. <p>Results of the home test should be documented at home, which should be submitted weekly for collation at the organization.</p>
<p>Spanish Society of Chemotherapy⁷⁰</p> <p>Recommendations for use of antigenic tests in the diagnosis of acute SARS-CoV-2 infection in the second pandemic wave</p> <p>October 2020</p>	Spain	Consensus document	<p>A multidisciplinary group of experts provided proposed algorithms for the use of antigen testing in a variety of situations including primary care, evaluation of close contacts, pediatric primary care, pediatric emergency care, pediatric close contacts (including schools), emergency settings, and sociosanitary centres. These algorithms were presented as flow charts for each scenario.</p>
Molecular tests			
<p>Managing COVID-19⁴⁹</p> <p>Manitoba</p> <p>November 24, 2020</p>	Canada	Interim guidance	<p>Guidance for testing with the Abbott ID NOW COVID-19 assay (rapid molecular test):</p> <ul style="list-style-type: none"> • can only be used for symptomatic people within 7 days of symptoms • recommended for use in high-prevalence settings • can be used to support urgent decision-making in high-risk settings • can be used in remote and isolated areas (with high turnaround times due to transportation issues) • may be useful for decision-making in high-consequence settings (e.g., shelters) • do not use the Abbott ID NOW COVID-19 assay for asymptomatic testing (except under consultation with public health medical microbiology)

Source	Country	Publication type	Recommendations and/or guidance
			<p>Testing considerations:</p> <ul style="list-style-type: none"> everyone offered this rapid molecular test should have two swabs taken, so that confirmation of results can be offered with another test a positive rapid molecular test can be treated as positive a negative rapid molecular test should be treated as presumptive negative and must isolate until laboratory results confirm the result
Rapid PoCs tests (general)			
<p>Rapid testing⁵¹ IDSA (Infectious Diseases Society of America) November 20, 2020</p>	US	Guideline	<p>IDSA guideline make no recommendations for or against using rapid tests versus standard RNA testing in symptomatic individuals suspected of having COVID-19 citing knowledge gaps.</p> <p>The report also noted the uncertainty about the effectiveness of rapid tests in real-life clinical space particularly among asymptomatic individuals.</p>
<p>Public Health England⁵⁰ Rapid PoC tests for use in community pharmacies or at home May 11, 2020</p>	Europe	Guidance	<p>Current view by Public Health England is that the use of rapid PoC tests is not advised.</p> <p>Evidence: “Currently there is no published evidence about the suitability of these rapid point-of-care tests for diagnosing COVID-19 infection in a community setting.”</p>

AHS = Alberta Health Services; EU/EEA = European Union/European Economic Area; FDA = US Food and Drug Administration; PCR = polymerase chain reaction; PoC = point of care; RNA = ribonucleic acid; RT-PCR = reverse transcription polymerase chain reaction.

Table 5: Test Performance of Rapid Point-of-Care Tests

First author, country (If reported)	PoC rapid test used ^a	Test performance	Setting	Population
Systematic review				
Dinnes ²² International	Rapid Antigen Test (5 studies) <ul style="list-style-type: none"> • Beijing Savant FIA • Coris Bioconcept CGIA • Liming CGIA • RapiGEN CGIA • Shenzhen Bioeasy FIA • In-house FIA Rapid Molecular Tests; 13 studies <ul style="list-style-type: none"> • Abbott — ID NOW • Cepheid — Xpert Xpress • Diagnostics for the Real-World — SAMBA II • Mesa Biotech —Accula 	Rapid Antigen Test (based on hypothetical cohort of 1,000 patients): <p>5% prevalence:</p> PPV 85% (68% to 95%) NPV 98% (97% to 99%) <p>10% prevalence:</p> PPV 92% (82% to 97%) NPV 95% (94% to 97%) <p>20% prevalence:</p> PPV 97% (91% to 99%) NPV 90% (88% to 92%) <p>Rapid Molecular Test (based on hypothetical cohort of 1,000 patients):</p> 5% prevalence: PPV 83% (71% to 91%) NPV 100% (99% to 100%) <p>10% prevalence:</p> PPV 90% (83% to 95%) NPV 99% (99% to 100%) <p>20% prevalence:</p> PPV 95% (92% to 98%) NPV 99% (98% to 99%)	ER; mixed; unclear	Individuals suspected of COVID-19

First author, country (If reported)	PoC rapid test used ^a	Test performance	Setting	Population
Primary studies				
Albert ⁷ Spain	Rapid Antigen Test <ul style="list-style-type: none"> • Panbio – COVID-19 Ag Rapid Test 	NPV = 99% (5% prevalence) and 97.9% (10% prevalence)	Primary care centre	Symptomatic
Cerutti ⁵² Italy	Rapid Antigen Test <ul style="list-style-type: none"> • SD-Biosensor 	PPV = 100% (in high prevalence) and 97.9% (in low prevalence) NPV = 73.6% (in high prevalence) and 100% (in low prevalence)	ER (high prevalence); travel (low prevalence) This study also simulated test performance over a range of prevalence (0.5% to 10%)	Symptomatic patients presenting to ER and asymptomatic travellers returning from high-risk countries (Croatia, Spain, Malta)
Fenollar ⁸ France	Rapid Antigen Test <ul style="list-style-type: none"> • Panbio – COVID-19 Ag Rapid Test 	PPV = 95.6% NPV = 72.2%	Hospital	NR
Fournier ¹⁰ France	Rapid Molecular Test <ul style="list-style-type: none"> • VitaPCR RT-PCR 	PPV = 88.6% NPV = 99.7%	Health care centre	NR
Linares ⁹ Spain	Rapid Antigen Test <ul style="list-style-type: none"> • Panbio – COVID-19 Ag Rapid Test 	Higher sensitivity of tests was found < 7 days of symptom onset compared to more days	Hospital	Primarily symptomatic
Porte ⁵³ Chile	Rapid Antigen Test <ul style="list-style-type: none"> • Shenzhen Bioeasy FIA 	Test sensitivity was higher 0-7 days post-symptom onset, compared with days 8-12. Higher viral loads were associated with higher sensitivity	Private Medical Centre (hospital)	Symptomatic
Scohy ¹¹ Belgium	Rapid Antigen Test <ul style="list-style-type: none"> • Coris COVID-19 Ag Respi-Strip 	Higher viral loads (PCR Cycle Threshold < 25) were associated with better detection	Hospital	Symptomatic and asymptomatic
Young ⁵⁴ US	Rapid Antigen Test <ul style="list-style-type: none"> • BD Veritor System for Rapid Detection of SARS-CoV-2 	High (>80%, based on FDA-EUA acceptance criteria) positive test agreement compared with Lyra PCR	NR	Symptomatic

First author, country (If reported)	PoC rapid test used ^a	Test performance	Setting	Population
		<p>standard at days 0 to 6 post-symptom onset; 76.3% at day 7 post-symptom onset</p> <p>High negative test agreement with Lyra PCR standard (100% days 0-5, 99.5% days 6-7 post symptom onset)</p> <p>PPV: 100% 0 to 5 days post-symptom onset, 96.6% in the 0 to 6 day group and 96.7% in the 0 to 7 day group.</p> <p>NPV: Ranged from 96.8% to 96.2% up to 6 days post-symptom onset and 95.9% in the 0 to 7 day group.</p> <p>Higher positive test agreement in patients with 2 or more symptoms at days up to 6 days post-symptom onset, compared with patients with one symptom.</p>		

Ag = antigen; CGIA = colloidal gold immunoassay; ER = emergency room; FIA = fluorescent immunoassay; NPV = negative predictive value; NR = not reported; PoC = point of care; PPV = positive predictive value; RT-PCR = reverse transcription polymerase chain reaction.

^a RT-PCR reference standard for all studies.