Canadian Journal of Health Technologies

CADTH

June 2022 Volume 2 Issue 6

CADTH Horizon Scan

# Self-Collection of Nose and Throat Swab Samples for SARS-CoV-2 Antigen Testing

Emerging Health Technologies

CADTH

**Authors:** Michelle Clark, Yan Li, Quenby Mahood, Melissa Severn

**ISSN:** 2563-6596



**About CADTH:** CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

**Funding:** CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

CADTH

## Table of Contents

CADTH

# List of Tables

## Key Messages

- The emergence of new variants of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has raised questions about the accuracy of currently available rapid antigen detection tests (RADTs) for the detection of these variants using the currently authorized sampling methods.
- Six Canadian provinces and 2 international jurisdictions have formally recommended people swab both their throat and nose when performing a RADT in response to the emergence of the Omicron variant. The evidence used to support these decisions was not clearly reported.
- Three pre-print non-peer reviewed publications (1 from Canada, 2 from the Netherlands) were identified regarding the diagnostic accuracy and clinical utility of RADTs using dual nasal and throat self-collected sample for suspected COVID-19. No relevant studies were identified that included children younger than 16 years old.
- Findings from these publications indicate that using self-collected combined nasal plus throat samples, instead of self-collected nasal samples for RADTs, resulted in greater detection rates without impacting true negative rates. Furthermore, combined nasal plus throat sampling is associated with high participant acceptability and tolerability, ease of use, and low incidence of harms (when reported). However, the limitations of these publications (e.g., non-peer reviewed pre-prints; dual nasal and throat sampling with swabs approved for nasal sampling only) should be taken into consideration when interpreting these findings.
- As new variants emerge and real-world clinical evaluations are published, regulatory bodies and/or RADT manufacturers could consider reassessing sampling methods, suitable swab types, and testing instructions.

## Introduction

At the end of 2021, a number of variants of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19 disease, were identified.[1] Concerns were raised as to whether the available rapid antigen detection tests (RADTs) would be able to identify the new variants as accurately as previous variations of the virus that were in circulation when the tests were developed.[1] The Omicron variant, in particular, has raised some concerns with regard to testing. Symptomatic infection with Omicron is commonly characterized by a sore throat among other cold-like symptoms. Early laboratory evidence suggests that Omicron primarily infects the upper airways, having a diminished affinity for lung tissue relative to Delta, which may contribute in part to reduced severity of infection. Anecdotal reports of people failing to test positive on RADTs despite displaying symptoms of COVID-19 suggested that these tests may be less accurate at identifying people infected with the Omicron variant and have potentially reduced public confidence in the accuracy of the tests. Other early data indicate that viral load may peak in saliva samples 1 to 2 days before nasal swab collections.

The objective of this report is to conduct a scan of Canadian and international jurisdictions to determine where recommendations for testing have been modified in response to the Omicron variant and to outline any evidence used to support those policy changes. Additionally, an overview of clinical evidence regarding the accuracy of dual oropharyngeal

and nasal swabbing for self-collection of samples for RADTs will be conducted to determine if dual swabbing methods for RADTs are as accurate as nasal swabbing alone.

## Methods

A limited literature search was conducted by 2 information specialists on key resources including MEDLINE, Embase, the Cochrane Database of Systematic Reviews, the international HTA database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were COVID-19 and rapid antigen detection tests and mouth swabs. The search was completed on May 9, 2022 and limited to English language documents published since January 1, 2021.

This report is not a systematic review and does not involve critical appraisal or include a detailed summary of study findings. Rather, it presents an overview of the technology and available evidence. This report is not intended to provide recommendations for or against a particular technology. 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 continues to change and grow rapidly.

One author screened the literature search results and reviewed the full text of all potentially relevant studies regarding clinical effectiveness and diagnostic test accuracy. A second author reviewed grey literature sources to identify current testing guidance. Studies were considered for inclusion if the intervention was RADT using self-collected dual nasal and oropharyngeal samples and contained relevant diagnostic accuracy and/or clinical utility outcomes. Studies that did not meet eligibility criteria (e.g., samples collected by health care professional; oropharyngeal swabbing only without nasal swabbing) are presented in the Related Developments section. Conference abstracts and grey literature were included when they provided additional information to that available in the published studies.

## How It Works

Antigen tests for SARS-CoV-2 use lateral flow immunoassays to detect the presence of viral proteins and identify a current infection. The self-collected tests require a sample to be collected with a swab from inside the nostril (nose swab) or posterior nasopharynx (nasopharyngeal swab). After collection, the swab is mixed in a liquid reagent which is then applied to the testing device. They are often referred to as rapid tests because the results are typically available in less than an hour, with many at-home tests providing results in around 15 minutes. Rapid antigen testing is not new. These types of tests are used for point-of-care diagnosis of other respiratory illnesses like influenza, respiratory syncytial virus, and pneumonia, as well as other infections such as group A streptococcus and malaria.[2]

## Availability in Canada

As of May 17, 2022, Health Canada has provided emergency use authorization to 40 rapid antigen tests and 15 tests with self-collected samples.[3] These tests were authorized based on the information submitted by the test manufacturers and, in most cases, the test performance was established using nasal swab samples.[3]

In Canada, tests for SARS-CoV-2 detection procured by the federal, provincial, and territorial governments have been distributed at no cost to the public. RADTs are also available for individuals to purchase online. The specific tests procured by governments may not be the same as those available for purchase. For additional information on tests that have been authorized for use in Canada, Health Canada publishes a list of Authorized COVID-19 Medical Devices.

## Current Practice

### Canada

As the pandemic has continued, the availability of reverse transcriptase polymerase chain reaction (RT-PCR) testing, the gold standard for the detection of SARS-CoV-2, has become limited in most Canadian jurisdictions. Self-administered RADTs give people the option to test themselves when they are concerned about the potential of a SARS-CoV-2 infection. With each new variant, questions have been raised regarding whether the results obtained from self-testing remain reliable.

In Canada, RADTs have been procured by the federal, provincial, and territorial governments. The provincial and territorial health ministries can provide their own guidance regarding the use of RADTs independent from the federal government. As of early 2022, the Government of Canada recommends RADTs be used in accordance with the directions provided by the manufacturer.[4] In response to the potential change in accuracy of RADTs to the Omicron variant, some provinces have issued guidance recommending people using RADTs swab both their throat and nose when obtaining a sample for testing. The most up-to-date recommendations are provided in Table 1. Six provinces have recommended a switch to dual nasal and throat swabbing for RADT sample collection.[5-10] In most cases, the evidence used to inform the change in the recommendations was not publicly available. The data that was provided to support the change in recommendations was largely gathered from non-peer reviewed pre-prints of clinical studies.

### International

Internationally, 2 countries (Norway and Israel) were identified that have formally recommended that people use combined throat and nasal swabbing for RADT sample collection.[21,22] Specific evidence to support the change in recommendation was not publicly provided in either country. The results of the international scan are summarized in Table 2.

In the UK, 1 of the 4 tests distributed by the National Health Service Test and Trace program included manufacturer instructions to swab both tonsils and 1 nostril.[23] The DHSC COVID-19 Self-Test is manufactured under contract to DHSC by Xiamen Biotime Biotechnology Co Ltd.

The test was granted an exceptional use authorization by the UK Medicines and Healthcare Products Regulatory Agency to allow the test to be used with self-collected samples.[24] This test did not receive authorization after review by the FDA[24] and is not authorized for use by Health Canada as of the writing of this report.[3]

The FDA continues to recommend people use authorized RADTs according to the manufacturer's instructions.[25] In September 2021, the FDA notified SARS-CoV-2 testing manufacturers that they are now required to routinely monitor new viral variants and assess the potential impact those variants might have on the performance of their RADTs.[25] If the manufacturer identifies any risk to their test's established performance caused by a variant, they are required to notify the FDA.[25]

## Table 1: Provincial and Territorial Recommendations for Swabbing Sites as of May 2022

| Province or territory | Recommendation | Evidence provided to support change in recommendation |
|---|---|---|
| **Newfoundland and Labrador**[5] | Combined swab | No publicly available supporting evidence was identified |
| **Prince Edward Island**[6] | Combined swab | No publicly available supporting evidence was identified |
| **Nova Scotia**[7] | Combined swab | Nova Scotia study[11,12] |
| **New Brunswick**[13] | No direction provided | NA |
| **Quebec**[8] | Combined swab | None |
| **Ontario**[9] | Combined swab | Ontario Science Table Report[14] |
| **Manitoba**[15] | Nasal swab | NA |
| **Saskatchewan**[10] | Combined swab | No publicly available supporting evidence was identified |
| **Alberta**[16] | No direction provided | NA |
| **British Columbia**[17] | Nasal swab | NA |
| **Northwest Territories**[18] | No direction provided | NA |
| **Yukon**[19] | Per manufacturer | NA |
| **Nunavut**[20] | Per manufacturer | NA |

Combined = dual swab of mouth and/or throat and nose; NA = not applicable.

## Table 2: International Recommendations for Swabbing Sites as of May 2022

| Country | Recommendation | Evidence provided to support change in recommendation |
|---|---|---|
| **US**[26] | Per manufacturer | NA |
| **UK**[27] | Per manufacturer | DHSC COVID-19 Self-Test (Rapid Antigen Test) instructions direct users to swab both tonsils and 1 nostril |
| **Australia**[28] | Per manufacturer | NA |
| **New Zealand**[29] | Per manufacturer | NA |
| **Norway**[21] | Combined swabbing for adults | No publicly available supporting evidence was identified |
| **Israel**[22] | Combined swabbing | No publicly available supporting evidence was identified |

Combined = dual swab of mouth and/or throat and nose; NA = not applicable.

## What Is the Evidence?

Three pre-print, non-peer reviewed publications on non-randomized studies (1 conducted in Canada,[12] 2 conducted in the Netherlands[30,31]) were identified regarding the diagnostic accuracy and clinical utility of RADTs using dual nasal and throat self-collected sample for suspected COVID-19.

Authors of the Canadian study compared results from 3 sampling methods (i.e., nasal, throat, and combined nasal plus throat swab) using Abbott Panbio (authorized by Health Canada and the FDA).[12] During a 7-day period in 2022 (dominant variant reported as Omicron BA.1.1.529), 1,472 asymptomatic community members (age-specific criteria was not reported, participants were described as adults) attending an urban testing centre consented to participate in this study. Samples were self-collected at the testing centre while under observation and guidance by trained volunteers. Subsequently, test results were interpreted by the trained volunteers.

In the first of 2 studies from the Netherlands, 6,497 symptomatic participants (aged ≥ 16 years) attending testing centres received RADTs to be performed at home with self-collected samples (nasal or combined nasal plus throat swab) without external observation or guidance.[31] Test results were interpreted by the participants according to manufacturers' instructions. The 3 RADTs investigated in this study were MPBio, Siemens Clinitest (FDA-authorized, Health Canada authorized), and Acon Flowflex (FDA-authorized); however, combined nasal plus throat sampling was not performed for the Acon Flowflex test. The relevant diagnostic accuracy data were collected from January 12, 2022 to February 10, 2022 (dominant variant reported as Omicron BA.1).

In the second study from the Netherlands, 7,196 health care workers (aged ≥ 18 years; 79.8% symptomatic; 20.2% asymptomatic) employed at participating hospitals and long-term care facilities were asked to self-collect samples (nasal or combined throat plus nasal swab) and interpret test results without external guidance.[30] The majority (76.1%) of the health care workers were medically-trained. The remaining proportion of health care workers consisted of supportive, office, and volunteer workers. Testing was performed in a dedicated room at the participating facility. The study was conducted between October 31, 2020 and February 2, 2021 (Alpha, Delta, and Omicron variants were reported as not yet observed in the Netherlands).

No studies were identified regarding the diagnostic accuracy and clinical utility of RADTs using dual nasal and throat sample collection for suspected COVID-19 in children under the age of 16 years.

### Diagnostic Accuracy

Diagnostic accuracy data, along with key study characteristics (e.g., dominant variant) and sampling procedures (when reported), are presented in Table 3. Detailed sampling procedures for combined throat plus bilateral nasal swabbing was reported in 1 of the 2 studies from the Netherlands (refer to the footer in Table 3).[30] In all 3 studies, RT-PCR testing was used as the reference standard.[12,30,31] Findings from the 3 studies suggested that combined nasal plus throat sampling for RADTs improved detection rates without having a negative impact on the specificity rates when compared to nasal sampling.[12,30,31]

## Participant Acceptability and Experience

In the Canadian study, participant acceptability to self-collected throat swabbing was high; as about 6% of eligible individuals refused to participate (unclear if percentage is for all eligible individuals attending the testing centre or those asked to provide combined nasal plus throat sample).[12] Furthermore, tolerability to self-collected throat and combined nasal plus throat

## Table 3: Summary of Rapid Antigen Detection Test Diagnostic Accuracy

| Study citation,[a] country | Rapid antigen detection test | Swab type | Sensitivity (95% CI) | Specificity (95% CI) | Presence of symptoms | Study time frame (dominant subvariant) |
|---|---|---|---|---|---|---|
| **Goodall et al. (2022)[12]**<br>**Canada** | Abbott Panbio[b] | Nasal (bilateral) swab[c]<br>Combined nasal[d] + throat swab (sampling procedure NR) | 68.4% (51.4 to 82.5%)<br>81.6% (65.7 to 92.3%) | 100.0% (99.2 to 100.0%)<br>100.0% (99.2 to 100.0%) | Asymptomatic | Seven days in January 2022 (specific time frame NR)<br>(Omicron BA.1) |
| **Schuit et al. (2022)[31]**<br>**Netherlands** | MPBio<br>Siemens Clinitest[e] | Nasal (bilateral) swab[f]<br>Combined nasal[d] + throat (sampling procedure NR)<br>Nasal (bilateral) swab[g]<br>Combined nasal[d] + throat (sampling procedure NR) | 69.9% (65.1 to 74.4%)<br>83.0% (78.8 to 86.7%)<br>70.2% (65.6 to 74.5%)<br>77.3% (72.9 to 81.2%) | 98.8% (97.3 to 99.6%)<br>97.8% (94.3 to 99.4%)<br>99.3% (97.6 to 99.9%)<br>97.0% (93.9 to 98.8%) | Symptomatic | January 12, 2022 to February 10, 2022<br>(Omicron BA.1) |
| **Zwart et al. (2022)[30]**<br>**Netherlands** | BD Veritor[b]<br>Roche SD Biosensor[b] | Nasal (bilateral) swab[h]<br>Combined throat + nasal (bilateral) swab[i]<br>Combined throat + nasal (bilateral) swab[i] | 50.3% (42.8 to 57.7%)<br>61.5% (56.6 to 66.3%)<br>74.2% (66.4 to 80.9%) | 99.7% (99.3 to 99.9%)<br>99.9% (99.6 to 100%)<br>99.7% (99.3 to 99.9%) | Symptomatic (79.8%); asymptomatic (20.2%) | October 31, 2020 to February 2, 2021<br>(Circulation of Alpha, Delta, and Omicron variants was not yet observed in the Netherlands) |

CI = confidence interval; NR = not reported.

[a]= Study citations are organized in alphabetical order by the primary author's last name.

[b]= Authorized by Health Canada and the FDA.

[c]= Sampling according to manufacturer's instructions (additional details NR).

[d]= Bilaterality of nasal swab NR.

[e]= Authorized by the FDA and Health Canada – Health Canada authorization listed under Healgen Scientific, LLC

[f]= Sampling procedure for nasal swab (MPBio): Insert the swab into 1 nostril by a minimum of 2.5cm and rotate the swab 3 to 4 times. Repeat for the second nostril.

[g]= Sampling procedure for nasal swab (Siemens Clinitest): Insert the swab into 1 nostril by 2 to 4cm and rotate the swab 5 times. Repeat for the second nostril.

[h]= Sampling procedure for nasal swab (BD Veritor): Insert the swab into 1 nostril by a minimum of 2.5cm and rotate the swab 5 times. Repeat for the second nostril.

[i]= Sampling procedure for combined throat plus nasal swab (BD Veritor and Roche SD Biosensor): Stroke the swab along the tonsils and all the way into the back of the throat. Do not touch the inside of the cheeks or the tongue with the swab. Then, insert the same swab into 1 nostril by a minimum of 2.5cm and rotate the swab 5 times. Repeat for the second nostril.

swabbing appeared to be high as no participants expressed preference to 1 sampling method over another (additional details not reported).

In the first of the 2 studies from the Netherlands, up to 3% and 5.5% of participants in the nasal swab and combined nasal plus throat swab groups, respectively, reported issues with performing and/or interpreting the at-home tests.[31] It appeared that the higher percentage of participants experiencing issues in the combined nasal plus throat swab group was primarily attributed to participants being uncertain of how deep to swab or fearful of swabbing too far in the throat. Finally, compared to combined nasal plus throat swab groups, participants in the nasal swabbing groups more often responded that they correctly performed and interpreted the tests.

In the second of the 2 studies from the Netherlands, all 3 study groups of health care workers, self-testing at hospitals and long-term care facilities, rated the test difficulty level similarly (median score 8 on a scale of 1 to 10, with 10 being the easiest).[30] When asked if participants had doubts regarding their test result, 1.6% (BD Veritor, nasal swab), 1.6% (BD Veritor, combined throat plus nasal swab), and 1.1% (Roche SD Biosensor, combined throat plus nasal swab) responded that they had serious doubts. Lastly, when asked if participants would recommend their test to colleagues, 89.8% (BD Veritor, nasal swab), 93.3% (BD Veritor, combined throat plus nasal swab), and 93.1% (Roche SD Biosensor, combined throat plus nasal swab) were agreeable or partly agreeable.

## Safety

The swabs included in authorized RADT kits have been assessed and authorized only to be used to collect nasal specimens. The specifications (e.g., length, flexibility, breaking point, etc.) of the swabs included in test kits may not be adequate or safe to be use for a throat collection method.[26] The FDA has stated that the collection of throat swabs is more complicated than nasal swabs and the Centers for Disease Control and Prevention recommend that throat swabs be collected only by trained health care providers.[26]

Two of the 3 identified pre-print publications reported on safety considerations related to the use of swabs for combined nasal plus throat sampling.[12,31] In the Canadian study, 1 participant vomited while many participants (specific number not reported) experienced a gag reflex during self-swabbing of the throat.[12] 1 of the 2 studies from the Netherlands, combined nasal plus throat sampling was not performed for the Acon Flowflex test as the study investigators deemed the manufacturer-provided swab unsuitable for nasal plus throat sampling (rationale not reported).[31] Although the manufacturer-provided swabs in MPBio and Siemens Clinitest kits are not Conformité Européenne (CE) marked for combined nasal plus throat sampling, they were considered safe upon evaluation by a quality team, diagnostic regulation experts, and the Medical Ethical Committee Utrecht. Authors of the second of 2 studies from the Netherlands did not report on safety considerations regarding combined nasal plus throat sampling.[30]

While none of the 3 identified pre-print publications reported on risks of swallowing a swab during throat sampling, a published study presented a case of a man who had experienced a gag reflex resulting in him inadvertently ingesting the swab during at-home, self-administered testing using the GenBody RADT kit.[32] The patient presented to an otorhinolaryngology

department with stable vital signs and no signs of respiratory distress. Upon diagnostic imaging, the swab was removed with the use of a flexible gastroscope and polypectomy loop.

## Issues to Consider

Differences in study characteristics should be taken into consideration when assessing the overall findings from the 3 identified pre-print non-peer reviewed publications.[12,30,31] The 2 studies conducted in the Netherlands included some[30] or all[31] symptomatic participants, while the study conducted in Canada included all asymptomatic participants.[12] While all 3 studies involved self-collection of swab samples, participants in 1 study[12] had some coaching by trained volunteers and participants in 2 studies[30,31] did not have external guidance (i.e., error in the sampling process cannot be ruled out). Test results were interpreted by trained volunteers in 1 study,[12] while self-interpreted in 2 studies (i.e., error in the result reading process cannot be ruled out).[30,31] Additionally, as participants in 1 study were all health care workers, they likely have more experience with rapid testing compared to laypersons.[30] Although 1 study presented stratified analyses (Table 2 of study publication) based on participant demographics such as vaccination status, previous SARS-CoV-2 infection, sex, and age group, between-group statistical comparisons were not conducted.[31] Furthermore, the 2 other studies did not present stratified analyses.[12,30] Since no studies included children younger than 16 years old, it is unclear if the findings are generalizable to this pediatric population. Additionally, it is also uncertain how children (and the caregiver collecting the sample, if applicable) would rate acceptability and tolerability to combined nasal plus throat swabbing. Finally, as there was no reporting of the presence of physical or cognitive disabilities in participants, it is unclear how disabilities would affect an individual's acceptability and tolerability of self-administered RADTs.

Two studies[12,31] were conducted during which Omicron BA.1 was the dominant subvariant, while 1 study was conducted before Alpha, Delta, and Omicron variants were observed.[30] With an increase in the Omicron BA.2 subvariant in Canada, it is unclear if findings from these 3 studies are entirely generalizable to current circumstances.[33] Based on a statement released by the FDA in December 2021, early data suggested that RADTs may have lower sensitivity for the detection of the Omicron variant; however, real-world data was lacking.[25] Findings from the National Microbiology Laboratory in Canada suggested that the performance of the Abbott Panbio and BTNX tests were comparable for the detection of Omicron and other SARS-CoV-2 variants.[12]

There may be various factors resulting in improved detection rates of RADTs using combined nasal plus throat samples versus nasal samples in the 3 identified pre-print publications.[12,30,31] While eating and drinking before performing a RADT may impact its performance, the authors of the 3 identified publications did not report on if the participants had recently consumed food and/or beverages. It may be possible that the Omicron variant is associated with preferential replication in different anatomic sites (i.e., altered tissue tropism).[12] Findings in a recent publication from South Africa suggested that, compared to nasal samples, saliva samples from Omicron-infected participants contained greater levels of detectable viral ribonucleic acid.[34]

## Related Developments

Three systematic reviews with meta-analyses pooled findings for the performance of RADTs using various sampling methods (e.g., nasopharyngeal, throat, saliva).[35-37] However, no subgroup analyses were presented on dual nasal and throat self-collected sampling, and it was unclear if samples were self-collected or collected by health care professionals. Findings from 2 published studies were not incorporated into this report as samples were collected by a health care professional instead of self-collection.[38,39] In 1 of these studies, the use of the Roche SD Biosensor test with nasopharyngeal sampling and combined nasal plus throat sampling resulted similar detection rates.[38] In the second study, the use of BD Veritor was compared to RT-PCR with both tests using combined nasal plus throat samples.[39] The sensitivity and specificity of the BD Veritor was determined to be 94.1% and 100%, respectively.

In a Canadian pre-print non-peer reviewed publication, study investigators compared molecular detection (i.e., nucleic acid amplification testing [NAAT] based on transcription mediated amplification [TMA] or RT-PCR) of the Omicron variant using nasopharyngeal swab samples to combined nasal plus throat swab samples.[11] Findings from this study suggested that both sampling methods resulted in similar NAAT sensitivity (nasopharyngeal sample: 89.1%; combined sample: 98.4%; P = 0.052) for the Omicron variant, which supports the ongoing use of either sampling methods for the molecular detection of SARS-CoV-2. Meanwhile, in a pre-print publication from South Africa, molecular detection of the Omicron variant differed between saliva (100% positive percent agreement [PPA]) and nasal swabs (86% PPA), which suggested increased detection with saliva samples.[40] As of early April 2022, the British Columbia Centre for Disease Control is conducting a validation study to help guide their approach in sampling methods for RADTs.[41]

## Conclusion

Six Canadian provinces and 2 international jurisdictions have formally recommended people swab both their throat and nose when performing a RADT in response to the emergence of the Omicron variant. The evidence used to support these decisions was not clearly reported.

In this report, 3 pre-print non-peer reviewed publications were identified regarding the diagnostic accuracy and clinical utility of RADTs using dual nasal and throat self-collected samples for individuals (aged ≥ 16 years) with suspected COVID-19.[12,30,31] All 3 studies involved RADTs that are authorized for use in Canada (i.e., Abbott Panbio,[12] Siemens Clinitest,[31] BD Veritor,[30] and Roche SD Biosensor[30]). Overall, findings from the 3 studies suggested that, compared to nasal sampling, combined nasal plus throat sampling for RADTs improved detection rates without negatively impacting specificity rates.[12,30,31]

In the Canadian study, participant acceptability and tolerability to self-collected throat swabbing appeared to be high.[12] In the second study, up to 5.5% of participants in the combined nasal plus throat swab groups experienced issues with performing and/or interpreting the RADTs.[31] In the third study, all study groups rated the test difficulty level similarly (median score 8 on a 1 [most difficult] to 10 [easiest] scale).[30]

No studies were identified that included children younger than 16 years of age. Furthermore, differences in study characteristics in the 3 identified publications should be taken into consideration when assessing the overall findings.[12,30,31] While all 3 studies involved self-collection of samples, participants in 1 study[12] were provided some coaching on sample collection and had their results interpreted by trained volunteers. Participants in another study were all health care workers, which may have had an impact on sample quality and result interpretation.[30] Finally, 1 study was conducted during a period when the circulation of Alpha, Delta, and Omicron variants was not yet observed in the Netherlands.[30]

Currently, many publicly available RADTs are based on nasal swabbing only (i.e., not approved for throat swabbing).[12] There may be potential for invalid results or safety issues if a testing kit is used in a way that deviates from the manufacturer's instructions.[12] Manufacturers could consider reevaluating sampling methods, suitability of included swabs, and testing instructions. As new variants emerge, real-world clinical evaluations on the performance of RADTs, involving a broader range of participants (e.g., small children, people living with physical and/or cognitive disabilities), may provide an expanded knowledge base that could help decision-makers in assessing the role of rapid tests as part of public health measures.

# References


1. Government of Canada. RADTs and variants of concern. *Interim guidance on the use of rapid antigen detection tests for the identification of SARS-CoV-2 infection.* 2021; https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/use-rapid-antigen-detection-tests.html#a4.4.1. Accessed 2022 May 12.
2. Abbott. BinxaxNOW™ product demo library: BinaxNOW™ Legionella Urinary Antigen Card demo video. 2022; https://www.globalpointofcare.abbott/en/support/product-demos/binaxnow.html. Accessed 2022 May 16.
3. Health Canada. List of authorized testing devices. *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#a4. Accessed 2022 May 10.
4. Government of Canada. Self-testing for COVID-19. *Information for patients: a guide to self-testing for COVID-19*. Ottawa (ON): Government of Canada; 2022: https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/testing-screening-contact-tracing/information-patients-guide-self-testing.html#a2. Accessed 2022 May 16.
5. Government of Newfoundland and Labrador. COVID-19: testing: how to use rapid self-tests: instructions. 2022; https://www.gov.nl.ca/covid-19/testing/how-to-use-rapid-self-tests/instructions/. Accessed 2022 May 10.
6. 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 May 10.
7. Nova Scotia Health. Nova Scotia Health research leads to new recommendation for rapid test swabbing technique that improves accuracy. 2022; https://www.nshealth.ca/news/nova-scotia-health-research-leads-new-recommendation-rapid-test-swabbing-technique-improves. Accessed 2022 May 10.
8. Using rapid tests. Québec City (QC): Government of Québec; 2022: https://cdn-contenu.quebec.ca/cdn-contenu/sante/documents/Problemes_de_sante/covid-19/21-210-203WA_Feuillet_Guide-Tests-rapides.pdf?1650394351. Accessed 2022 May 10.
9. COVID-19 rapid antigen tests: how to collect a sample. Toronto (ON): Ontario Health; Ontario Ministry of Health; 2022: https://www.ontariohealth.ca/sites/ontariohealth/files/2022-02/COVID-19RapidAntigenTests-HowtoCollectaSample.pdf. Accessed 2022 May 10.
10. Saskatchewan Health Authority. Throat and nares (nasal) swabbing for rapid antigen tests. 2022; https://www.saskhealthauthority.ca/news-events/news/throat-and-nares-nasal-swabbing-rapid-antigen-tests. Accessed 2022 May 10.
11. Patriquin G, LeBlanc JJ, Gillis HA, McCracken GR, Pettipas JJ, Hatchette TF. Combined oropharyngeal/nares and nasopharyngeal swab sampling remain effective for molecular detection of SARS-CoV-2 Omicron variant [non peer-reviewed preprint]. *medRxiv.* 2022. 10.1101/2022.02.13.22270891. Accessed 2022 May 17.
12. Goodall BL, LeBlanc JJ, Hatchette TF, Barrett L, Patriquin G. Investigating sensitivity of nasal or throat (ISNOT): a combination of both swabs increases sensitivity of SARS-CoV-2 rapid antigen tests [non peer-reviewed preprint]. *medRxiv.* 2022. 10.1101/2022.01.18.22269426. Accessed 2022 May 17.
13. Government of New Brunswick. About at-home COVID-19 rapid point of care tests. 2022: https://www2.gnb.ca/content/gnb/en/corporate/promo/covid-19/about-covid-19/testing-tracing.html#7. Accessed 2022 May 10.
14. Ontario COVID-19 Science Advisory Table. Use of rapid antigen tests during the Omicron wave. 2022; https://covid19-sciencetable.ca/sciencebrief/use-of-rapid-antigen-tests-during-the-omicron-wave/. Accessed 2022 May 10.
15. Government of Manitoba. Information for Manitobans: COVID-19 Rapid Antigen Tests (RATs). 2022; https://www.gov.mb.ca/covid19/testing/rat.html. Accessed 2022 May 10.
16. Government of Alberta. How to test. *Rapid testing at home.* 2022; https://www.alberta.ca/rapid-testing-at-home.aspx#jumplinks-3. Accessed 2022 May 10.
17. BC Centre for Disease Control. Rapid testing at home. 2022; http://www.bccdc.ca/health-info/diseases-conditions/covid-19/rapid-antigen-testing/rapid-testing-at-home. Accessed 2022 May 10.
18. COVID-19 public testing and guidance. Yellowknife (NT): Northwest Territories (NWT) Health and Social Services Authority; 2022: https://www.nthssa.ca/sites/nthssa/files/resources/cpho_covid_testing_and_guidance-13april2022.pdf. Accessed 2022 May 10.
19. Guidance for rapid antigen testing. Whitehorse (YT): Government of Yukon; Health and Social Services; 2022: https://yukon.ca/sites/yukon.ca/files/hss/hss-imgs/guidance_for_rapid_antigen_testing_jan-6.pdf. Accessed 2022 May 10.
20. Government of Nunavut. COVID-19 rapid antigen self tests. 2022; https://gov.nu.ca/https://gov.nu.ca/health/information/covid-19-novel-coronavirus/rapid-antigen-selftests. Accessed 2022 May 10
21. Folkehelseinstituttet. Oppdaterte råd om selvtest for covid-19 [Updated COVID-19 self-test advice]. 2022; https://www.fhi.no/nyheter/2022/oppdaterte-rad-om-selvtestforcovid-19/. Accessed 2022 May 10.
22. Lubell M. Swab throat too when using rapid COVID test, Israel's Health Ministry says. *Reuters.* 2022 Jan 10. https://www.reuters.com/world/middle-east/swab-throat-too-when-using-rapid-covid-test-israeli-health-official-says-2022-01-10/. Accessed 2022 May 10.
23. National Health Service. Your step-by-step guide to DHSC COVID-19 Self-Test (Rapid Antigen Test). London (UK): NHS; 2021: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1045088/COVID-19-self-test-throat-and-nose-instructions.pdf. Accessed 2022 May 12.
24. Pollock AM, Roderick P. Why all the secrecy around Innova lateral flow tests? *BMJ Opinion.* 2021 Jan 11; https://blogs.bmj.com/bmj/2021/07/11/why-all-the-secrecy-around-innova-lateral-flow-tests/. Accessed 2022 May 12.

25. United States Food and Drug Administration. SARS-CoV-2 viral mutations: impact on COVID-19 tests. 2022; https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery. Accessed 2022 May 12.
26. FDA issues guidance amid throat swab debate: 'tests should be used as authorized'. *NBC Chicago.* 2022 Jan 5. https://www.nbcchicago.com/news/local/fda-issues-testing-guidance-amid-omicron-throat-swab-debate/2721570/. Accessed 2022 May 10.
27. Government of the United Kingdom, UK Health Security Agency. How to do a coronavirus (COVID-19) rapid lateral flow test. 2022; https://www.gov.uk/guidance/covid-19-self-test-help. Accessed 2022 May 12.
28. Public Health Laboratory Network – Communicable Diseases Network Australia joint statement on SARS-CoV-2 rapid antigen tests. Canberra (AU): Public Health Laboratory Network; Communicable Diseases Network Australia; 2022: https://www.health.gov.au/sites/default/files/documents/2022/02/phln-and-cdna-joint-statement-on-sars-cov-2-rapid-antigen-tests.pdf. Accessed 2022 May 12.
29. How to use a rapid antigen test. Wellington (NZ): New Zealand Ministry of Health; 2022: https://www.health.govt.nz/system/files/documents/publications/ctc-handout-how-to-take-a-rat-6apr22.pdf. Accessed 2022 May 12.
30. Zwart VF, van der Moeren N, Stohr JJJM, et al. Performance of various lateral flow SARS-CoV-2 antigen self testing methods in healthcare workers: a multicenter study [non peer-reviewed preprint]. *medRxiv.* 2022. 10.1101/2022.01.28.22269783. Accessed 2022 May 18.
31. Schuit E, Venekamp RP, Hooft L, et al. Accuracy of COVID-19 self-tests with unsupervised nasal or nasal plus oropharyngeal self-sampling in symptomatic individuals in the Omicron period [non peer-reviewed preprint]. *medRxiv.* 2022. 10.1101/2022.03.24.22272891. Accessed 2022 May 18.
32. Molnar D, Zsigmond F, Helfferich F. Safety precautions for self-performed Severe Acute Respiratory Syndrome Coronavirus 2 tests: a case of a swallowed swab. *Cureus.* 2021;13(5):e15297. PubMed
33. Public Health Ontario. COVID-19 Omicron variant sub-lineage BA.2: evidence and risk assessment (up to date as of May 3, 2022). 2022; https://www.publichealthontario.ca/-/media/Documents/nCoV/voc/covid-19-omicron-risk-assessment.pdf?sc_lang=en. Accessed 2022 May 16.
34. Marais G, Hsiao NY, Iranzadeh A, et al. Improved oral detection is a characteristic of Omicron infection and has implications for clinical sampling and tissue tropism. *J Clin Virol.* 2022;152:105170. PubMed
35. Khalid MF, Selvam K, Jeffry AJN, et al. Performance of rapid antigen tests for COVID-19 diagnosis: a systematic review and meta-analysis. *Diagnostics (Basel).* 2022;12(1):04.
36. Ghasemi S, Harmooshi NN, Rahim F. Diagnostic utility of antigen detection rapid diagnostic tests for Covid-19: a systematic review and meta-analysis. *Diagn Pathol.* 2022;17(1):36. PubMed
37. Brummer LE, Katzenschlager S, McGrath S, et al. Accuracy of rapid point-of-care antigen-based diagnostics for SARS-CoV-2: an updated systematic review and meta-analysis with meta regression analyzing influencing factors [non peer-reviewed preprint]. *medRxiv.* 2022. 10.1101/2022.02.11.22270831. Accessed 2022 May 18.
38. Venekamp RP, Veldhuijzen IK, Moons KGM, et al. Detection of SARS-CoV-2 infection in the general population by three prevailing rapid antigen tests: cross-sectional diagnostic accuracy study. *BMC Med.* 2022;20(1):97. PubMed
39. Van der Moeren N, Zwart VF, Lodder EB, et al. Evaluation of the test accuracy of a SARS-CoV-2 rapid antigen test in symptomatic community dwelling individuals in the Netherlands. *PLoS ONE.* 2021;16(5):e0250886. PubMed
40. Marais G, Hsiao N-y, Iranzadeh A, et al. Saliva swabs are the preferred sample for Omicron detection [non peer-reviewed preprint]. *medRxiv.* 2021. https://www.medrxiv.org/content/medrxiv/early/2021/12/24/2021.12.22.21268246.full.pdf. Accessed 2022 May 18.
41. Weichel A. Should you swab your throat while taking a COVID-19 rapid test? Answers vary by jurisdiction. *CTV News.* 2022. https://bc.ctvnews.ca/should-you-swab-your-throat-while-taking-a-covid-19-rapid-test-answers-vary-by-jurisdiction-1.5849210. Accessed 2022 May 10.