EVIDENCE SYNTHESIS BRIEFING NOTE

TOPIC: SENSITIVITYAND USE OF RAPID ANTIGEN TESTS FOR SARS-COV-2 DELTA VARIANT

Information finalized as of Sept. 17, 2021.[a] This Briefing Note was completed by the Evidence Synthesis Unit (Research, Analysis and Evaluation Branch, Ministry of Health) in collaboration with members of the COVID-19 Evidence Synthesis Network. Please refer to the Methods section for further information.

Purpose: This note summarizes scientific and grey literature on the sensitivity, specificity, and use of rapid antigen diagnostic tests (RADTs) and reverse transcription-polymerase chain reaction (RT-PCR) testing for the Delta variant among symptomatic and asymptomatic populations, including children.

Key Findings: Many antigen and molecular rapid tests show high positive predictive values (PPV) and negative predictive values, reflecting higher a likelihood that a positive test result is a 'true' positive and a negative test result is a 'true' negative; however, these values are affected by the prevalence of the virus where the tests are conducted. This means that people who test negative for COVID-19 may still be infected with SARS-CoV-2.

- **RADT and RT-PCR Test Sensitivity**: Typically, the sensitivity of antigen tests is 30% to 40% lower than of RT-PCR tests, depending on whether tested subjects were symptomatic or asymptomatic. The lower sensitivity of RADTs is affected by several factors, such as specimen type, the timing of sampling, assay type, and viral load. Overall, clinical sensitivity varies from 28.9% to 98.3%, depending on assay, population characteristics, viral load, and symptom status.
    - Delta Variant: A study of the RADT BinaxNOW found this assay detected the highly infectious variants including the Delta variant, but test sensitivity decreased with decreasing viral loads.
    - Children: RADTs perform poorly in asymptomatically infected children but can successfully identify most COVID-19 infections in children with viral load levels that indicate they are likely to be infectious, especially in the first days of the illness.
- **Specificity of RADTs**: Specificity from individual studies ranged from 92.4% to 100.0% but these tests have shown a great sensitivity range (38.32 - 99.19%).
- **Symptomatic Testing**: In people with COVID-19 symptoms, test sensitivities are highest in the first week of illness when viral loads are higher. RADTs that meet appropriate criteria (e.g., from the World Health Organization) are best used when urgent decisions about patient care must be made, or where RT-PCR cannot be delivered in a timely manner.
- **Asymptomatic Testing in Low-Prevalence Settings**: If RADTs are used to screen asymptomatic cases in low-prevalence scenarios (e.g., in an area without an outbreak), a lower PPV may be the result.
  Jurisdictions' Experiences: Australia, Italy, the UK, and the US support the use RADTs. For example, in the UK, individuals are encouraged to do a rapid test twice a week; tests are available at test sites, pharmacies, schools, universities, and employer sites, and available for at-home use. Canadian guidance advises that mutations might arise, which may have a negative impact on the performance of RADTs.

Analysis for Ontario: No information identified.

Implementation Implications: The efficacy of any alternative testing strategies to complement nucleic acid-based assays must be carefully evaluated by independent laboratories prior to widespread implementation.

[a] This briefing note includes current available evidence as of the noted date. It is not intended to be an exhaustive analysis, and other relevant findings may have been reported since completion.

Supporting Evidence

The information in Table 1 is a summary of scientific evidence and jurisdictional experiences regarding the sensitivity, specificity and use of rapid antigen diagnostic tests (RADTs) for SARS-CoV-2 as compared with reverse transcription-polymerase chain reaction (RT-PCR) and in relation to the Delta variant for symptomatic and asymptomatic populations including children. Details from each of the cited sources can be found in the Appendix: Table 2 for research evidence on sensitivity and specificity of RADTs and Table 3 for jurisdictional information on the use of RADTs (without PCR confirmation).

Limitations

One study provided information about the sensitivity of RADTs in detecting the Delta variant. Furthermore, the methodological quality of most of the sources identified are unclear as the Research, Analysis, and Evaluation Branch does not have the expertise to make such assessments; methodological assessments published by other research groups are reported where available (e.g., AMSTAR).

Table 1: Sensitivity, Specificity and Use of Rapid Antigen Diagnostic Tests for SARS-CoV-2 Delta Variant

Scientific Evidence	The information in this section consists primarily of findings from four systematic reviews, and five reviews on the sensitivity and specificity of rapid antigen diagnostic tests (RADTs) for both symptomatic and asymptomatic populations.[b] Additional information was drawn from single studies that evaluated specific tests including three single studies that assessed the suitability of RADTs for children. • Many antigen and molecular rapid tests show high positive predictive values (PPV) and negative predictive values (NPV),[c] reflecting higher likelihoods that a positive test is a true positive and a negative test is a true negative, but these values are affected by the prevalence of the virus where the tests are conducted.[1,d] For example, PPVs suggest that confirmatory testing of those with positive results may be considered in low prevalence settings. Given the variable sensitivity of antigen tests, people who test negative may still be infected.[2] ○ **Comparison of RADT and RT-PCR Sensitivity**: Typically, the sensitivity of antigen tests is 30% to 40% lower than for RT-PCR tests, depending on whether tested subjects were symptomatic or asymptomatic.[3] The lower sensitive of RADTs is affected by several factors, such as specimen type, the timing of sampling, assay type, and viral load.[4] Overall, clinical sensitivity varies between 28.9% and 98.3%, depending on assay, population characteristics, viral load, and symptom status. Sensitivity in high-viral-load samples (cycle threshold ≤25) showed a considerable heterogeneity among the assays ranging from

[b] Sensitivity refers to a test's ability to designate an individual with disease as positive. A highly sensitive test means that there are few false negative results, and thus fewer cases of disease are missed. The specificity of a test is its ability to designate an individual who does not have a disease as negative. A highly specific test means that there are few false positive results (New York State Department of Health, 1999).

[c] Positive predictive value (PPV) is the probability that those testing positive have the condition. Negative predictive value (NPV): the probability that those testing negative do not have the condition (CADTH, 2020).

[d] Test specificity is an issue at lower prevalence of infection; a lower prevalence means lower PPV and a higher number of false positive results. As prevalence of infection in the community increases, the PPV of a test also increases, and the number of false positive results decreases. Conversely, sensitivity is a concern at higher prevalence; a higher prevalence means lower NPV and a higher number of false negatives. Thus, a test should be specific enough to minimize the proportion of cases erroneously diagnosed as positive in low prevalence settings, and sensitive enough to avoid missing a diagnosis as COVID-19 prevalence increases (Peeling et al., 2021).

66.7% to 100%.[5] Elsewhere, sensitivity from individual studies ranged from 37.7% to 99.2%.[6]

- Recommendation: The efficacy of any alternative testing strategies to complement nucleic acid-based assays must be carefully evaluated by independent laboratories prior to widespread implementation.[7]
- Delta Variant: A study of the RADT BinaxNOW found it detected the highly infectious variants including the Delta variant, but test sensitivity decreased with decreasing viral loads. According to the identified literature, sensitivity trended lower when devices were performed by patients/caregivers themselves compared to trained clinical staff, despite universally high usability assessments following self/caregiver-administration among different age groups.[8]
- Best Type of RADT: The best RADT sensitivity was found with anterior nasal sampling (75.5% to 79.9%), in comparison to other sample types (e.g., nasopharyngeal, 71.6% to 74.9%).[9]

- **Specificity of RADTs**: Specificity from individual studies ranged from 92.4% to 100.0% but these tests have shown a great range of sensitivities (38.32 - 99.19%).[10,e]
- **Symptomatic Testing**: RADTs vary in sensitivity. In people with signs and symptoms of COVID-19, sensitivities are highest in the first week of illness when viral loads are higher.[11,12,13] The assays shown to meet appropriate criteria[f] can be considered as a replacement for RT-PCR when immediate decisions about patient care must be made, or where RT-PCR cannot be delivered in a timely manner.[14,15] Reliable PPV require testing of symptomatic patients or asymptomatic individuals only in case of a high pre-test probability.[16]
- **Asymptomatic Testing**: A systematic review (March 2021) found that evidence for testing in asymptomatic cohorts was limited. Test accuracy studies cannot adequately assess the ability of RADTs to differentiate those who are infectious and require isolation from those who pose no risk, as there is no reference standard for infectiousness.[17] A study suggests that, compared with RT-PCRs, RADTs are less effective in asymptomatic populations.[18]
  - Low-Prevalence Testing: If RADTs are used to screen asymptomatic cases in low-prevalence scenarios, a lower positive predictive value of the result must be considered.[19,20] It is estimated that the likelihood of testing positive in asymptomatic individuals in schools, workplaces, mass gatherings, and travellers would be low (possibly 1 - 2·5%), unless they are in a COVID-19 outbreak area. A RADT with 80% sensitivity and 97% will result in NPVs of 99 - 100% which means that most people testing negative are likely to be true negatives.[21]
- **Testing in Specific Populations**: Information was identified about the use of RADTs for children, and for long-term care (LTC) residents.
  - Children: Three single studies reported on the sensitivity of RADTs for children finding that RADTs performed poorly in asymptomatically infected children.[22,23,24] One study found an overall suboptimal 66% sensitivity of an assay, ranging between 43% and 73% in asymptomatic and symptomatic children. However, among symptomatic children with high viral load (VL), the assay's sensitivity was reported to be only marginally lower than symptomatic adults with high VL.[25] It is suggested that RADTs can successfully identify

[e] Test performance does not appear dependent on the operator (Mistry et al., 2021).
[f] For example, the World Health Organization's priority target product profiles for COVID-19 diagnostics for 'acceptable' sensitivity ≥ 80% and specificity ≥ 97% (Dinnes et al., 2021).

	most COVID-19 infections in children with viral load levels likely to be infectious,[26] especially in the first days of the illness.[27] Serial rapid testing may help compensate for limited sensitivity in early infection.[28] ▪ LTC Residents: With the high rates of protection of vaccines against symptomatic and asymptomatic SARS-CoV-2 infection, the potential harms and costs of screen testing with RADTs among vaccinated LTC home staff likely outweigh the benefits.[29] ○ **Future Research**: A Canadian Institutes of Health Research (CIHR) grant application has been submitted by the Ontario SPOR Evidence Alliance to conduct a living systematic review and diagnostic test accuracy network meta-analysis to determine the most sensitive and/or most specific rapid test for COVID-19. It will include both antigen and molecular tests performed in any adult (symptomatic/ asymptomatic/exposed/unexposed/vaccinated/ unvaccinated) and in any setting for COVID-19.[30]
International	**Symptomatic Populations** • Australia: Trained health professionals or laboratory scientists use RADTs to test symptomatic patients.[31,g] RADTs are not intended for home testing, but may be in the future.[32] The Therapeutic Goods Administration (TGA) is undertaking a post-market review of all point-of-care and laboratory tests that identify individuals with COVID-19 to verify whether they can accurately detect emerging variants of concern (VoC).[h] As of August 31, 2021, there are 14 RADT test kits manufactured by different countries that have evidence to support their continued performance with various variants, with 13 of the 14 performing against the Delta variant. The review is ongoing and will be published here as it becomes available.[33] ○ Negative results, and some positive results, may require further testing by a nucleic acid test to confirm if a patient is infected with SARS-CoV-2.[34] **Asymptomatic Populations** • **United Kingdom**: Innova lateral flow devices (Biotime SARS-CoV-2 Lateral Flow Antigen Device) is a free test for asymptomatic individuals that provides a quick result using a device similar to a pregnancy test.[35] Tests are available at test sites, pharmacies, schools, universities, and employer sites, and are available for at-home use.[36] Individuals are encouraged to do a rapid test twice a week (every three to four days). If there is a positive result or the test sample could not be read, individuals should do a PCR test.[37] Test results should be reported online within 24 hours of being tested.[38] ○ Findings from three studies (two published by the UK government and one by Liverpool University) on the real-world use of lateral flow devices have confirmed their effectiveness under a variety of conditions (e.g., against VoC, patients with low/high viral loads, mass testing campaigns, hands of inexperienced users, different types of swabs), demonstrating their reliability and adaptability.[39] Specifically, post-market surveillance shows there is no significant difference in the devices' ability to detect the Delta and Alpha variants.[40] **Symptomatic and Asymptomatic Populations** • **United States**: As of September 2021, the COVID-19 Action Plan implements a six-pronged, national strategy to combat COVID-19 VoC, one of which is increasing the amount of testing. The production of rapid tests, including at-home tests, will be accelerated via the Defense

[g] Some states (e.g., Western Australia, South Australia) have prohibited or restricted use of RADTs as an acute illness diagnostic tool for COVID-19 (Therapeutic Goods Administration, Sept 10, 2021).

[h] The TGA is monitoring the emerging variants of SARS-CoV-2 with at least 5% prevalence in the global population (i.e., mutations that occur in at least 5% of each viral variant) and will keep monitoring these variants as they continue to mutate (TGA, Sept 8, 2021).

	Production Act and the CAD $2.4 billion procurement of 280 million tests from multiple manufacturers.[i] These tests will be available to support a range of needs, including long-term care facilities, community testing sites, critical infrastructure, shelters serving individuals experiencing homelessness, prisons and jails, and other vulnerable populations and congregate settings. To improve access to rapid tests for all consumers, top retailers that sell at-home, rapid COVID-19 tests (e.g., Walmart, Amazon) will offer to sell those tests at-cost for the next three months, so Americans will be able to buy these tests for up to 35% less.[41] ○ The Food and Drug Administration currently lists many RADTs for emergency use authorization. • **Italy:** On February 15, 2021, the Ministry of Health updated the indications regarding the use of RADTs, given the circulation of new variants of the virus, including Alpha and Gamma. Specifically, the new variants should still be detected by antigen tests; however, the situation will have to be closely monitored for other variants (i.e., from the UK and Brazil) RADTs may be used for: close contacts of a confirmed case without symptoms and without others at risk in their household; people displaying milder symptoms; and people arriving from countries at risk. Rapid tests are also the first choice in community screenings, and for those who voluntarily undergo the test for personal reasons, travel, or work needs.[42]
Canada	• The Government of Canada's interim guidance on the use of RADTs (as of Feb 23, 2021) highlights that VoC have two significant impacts in the potential for deployment of RADTs: ○ Mutations might arise that have a negative impact on the performance of the tests themselves. At the time of writing this guidance, this particular impact had not been observed but it remains an important consideration. Health Canada provides up-to-date risk assessments regarding the impact of VoC on diagnostic assays and requires certain criteria be met before authorizing an application of a RADT. ○ Users should remember that sequencing characterization cannot be done from a RADT device. As a result, it is important to ensure that individuals with a positive RADT result that may require further characterization (e.g., recent traveller, positive case of COVID-19 following vaccination) should still have a sample collected for PCR testing.[43] • According to Health Canada's guidance on testing for COVID-19 in vaccinated populations (August 2021), self-RADTs are not yet authorized for sale in Canada, but several self-RADTs are under consideration with potential regulatory decisions expected by Fall 2021. Depending on the size of a screening program, they may be the most feasible test to use because financial and human resource costs are reduced. As self-RADTs have lower sensitivity than RADTs, follow-up lab-based PCR tests to screen and sequence variants would be required to confirm in initial tests results.[44]
Ontario	• No information identified.

[i] The document reported a figure of USD $2 billion. The Canadian Dollar (CAD) amount was calculated using Purchasing Power Parities (PPPs) as published by the Organisation for Economic Co-operation and Development (OECD) for 2020 (1 United States dollar [USD] = 1.206 CAD). PPPs are the rates of currency conversion that eliminate the differences in price levels between countries (OECD, 2021).

Methods

The COVID-19 Evidence Synthesis Network is comprised of groups specializing in evidence synthesis and knowledge translation. The group has committed to provide their expertise to provide high-quality, relevant, and timely synthesized research evidence about COVID-19 to inform decision makers as the pandemic continues. The following members of the Network provided evidence synthesis products that were used to develop this Evidence Synthesis Briefing Note:

- Rapid Point-of-Care Testing for COVID-19. Ottawa: Canadian Agency for Drugs and Technologies in Health (CADTH); December 2020. (CADTH Horizon Scan).
- Ontario SPOR Evidence Alliance (September 17, 2021). Email communication.
- Ontario Health (September 15, 2021). Email communication.
- McMaster Health Forum (September 15, 2021). Email communication.
- Evidence Synthesis Unit, Research Analysis and Evaluation Branch (RAEB), Ontario Ministry of Health. September 20, 2021.

For more information, please contact the Research, Analysis and Evaluation Branch, Ontario Ministry of Health

Appendix

Table 2: Research Evidence on Sensitivity and Specificity of Rapid Antigen Diagnostic Tests for COVID-19

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
Systematic Review (preprint) April 5, 2021 [AMSTAR 5/11]	• None identified.	• None identified.	• Purpose: The main goal of this study was to determine the accuracy of rapid diagnostic tests (RADTs). • Results: This study found that generally RADTs have lower sensitivity than RT-PCR; this issue is affected by several factors such as type of specimen, the timing of sampling, type of assay, and viral load. • Implications: This research extends our knowledge of how to improve the sensitivity of RDTs to better diagnose of infected patients to address the controlling COVID-19 pandemic.	• Of the 20 studies included in the review, 11 (55%) evaluated nasopharyngeal swabs.	Ebrahimi, M., Harmooshi, N. N., & Rahim, F. (2021). Diagnostic utility of antigen detection rapid diagnostic tests for Covid-19: A systematic review and meta-analysis. *medRxiv*.
Systematic review (preprint) December 24, 2020 [AMSTAR 5/11]	• None identified.	• None identified.	• Overview: This review included 19 studies (ten peer-reviewed) presenting detailed clinical performance data based on 11,209 samples with 2,449 RT-PCR-positives out of study prevalence rates between 1.9–100% and between 50– 100% symptomatic samples. • Symptomatic Testing: Only two RADTs offered sufficient manufacturer-independent, real-world performance data supporting use for the detection of current SARS-CoV-2 infection in symptomatic or high-viral-load patient populations. Reliable positive predictive values require testing of symptomatic patients or asymptomatic individuals only in case of a high pre-test probability. • Asymptomatic Testing: If RADTs are used for screening of asymptomatic cases in low-prevalence scenarios, a lower positive predictive value of the result must be considered.	• Specificity: Overall specificity ranged, with one test outlier, between 92.4% (87.4–95.9) and 100% (99.7–100). • Sensitivity: Overall clinical sensitivity varied between 28.9% (16.4–44.3) and 98.3% (91.1–99.7), depending on assay, population characteristics, viral load, and symptom status. Sensitivity in high-viral-load samples (cycle threshold ≤25) showed a considerable heterogeneity among the assays ranging from 66.7% to 100%.	Hayer, J., Kasapic, D., & Zemmrich, C. (2021). Real-world clinical performance of commercial SARS-CoV-2 rapid antigen tests in suspected COVID-19: A systematic meta-analysis of available data as per November 20, 2020. *International Journal of Infectious Diseases.*
Systematic review	• Various	• None identified.	• This review found that the performance of lateral flow devices (LFDs) is heterogeneous and dependent on the manufacturer. Some perform with high specificity, but a great range of	• Sensitivity: Sensitivity from individual studies ranged from 37.7%	Mistry, D. A., Wang, J. Y., Moeser, M. E., Starkey, T., & Lee, L. Y. (2021). A

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
August 18, 2021			sensitivities were shown (38.32 - 99.19%). Test performance does not appear dependent on the operator. Potentially, LFDs could support the scaling up of mass testing to aid track and trace methodology and break the chain of transmission of COVID-19 with the additional benefit of providing individuals with the results in a much shorter time frame.	(95% CI 30.6-45.5) to 99.2% (95% CI 95.5-99.9). • Specificity: Specificity from 92.4% (95% CI 87.5-95.5) to 100.0% (95% CI 99.7-100.0).	systematic review of the sensitivity and specificity of lateral flow devices in the detection of SARS-CoV-2. *BMC Infectious Diseases*.
Systematic review & Meta-analysis (preprint) August 12, 2021	• Various	• None identified.	• Overview: This review included 133 analytical and clinical studies resulting in 214 clinical accuracy datasets with 112,323 samples. • Implications: This study found that RADTs detect most SARS-CoV-2-infected persons within the first week of symptom onset and those with high viral load. Thus, they can have high utility for diagnostic purposes in the early phase of disease, making them a valuable tool to fight the spread of SARS-CoV-2.	• Sensitivity: The pooled RADTs sensitivity was 71.2% (95% CI 68.2% to 74.0%). Testing in the first week from symptom onset resulted in substantially higher sensitivity (83.8%, 95% CI 76.3% to 89.2%) compared to testing after one week (61.5%, 95% CI 52.2% to 70.0%). ○ The best RADT sensitivity was found with anterior nasal sampling (75.5%, 95% CI 70.4% to 79.9%), in comparison to other sample types (e.g., nasopharyngeal, 71.6%, 95% CI 68.1% to 74.9%), although CIs were overlapping. • Specificity: The pooled DART specificity was 98.9% (95% CI 98.6% to 99.1%).	Bruemmer, L. E., Katzenschlager, S., Gaeddert, M., Erdmann, C., Schmitz, S., Bota, M., ... & Denkinger, C. M. (2021). The accuracy of novel antigen rapid diagnostics for SARS-CoV-2: A living systematic review and meta-analysis. *medRxiv*.

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
Review August 22, 2020 [AMSTAR 7/11]	• Seven tests.	• None identified.	• Based on moderate quality evidence, the use of rapid antigen tests (RADT) as a screening tool for COVID-19 is limited by its low sensitivity. Because of its overall low sensitivity and high uncertainty on its accuracy, limited use is recommended for diagnostic confirmation when RT-PCR is not available and for patients with high pre-test probability, such as suspected cases in hospitals. High quality validation studies are needed.[45]	• Sensitivity: Sensitivity estimates ranged from 0 to 94% in different studies and may have been affected by the study design, brand used, population being tested, reference standard or specimen used, and day of illness when the test was done. RADT tests have a low sensitivity of 49%. • Specificity: RADT tests have high specificity of 99%.	Henrian, H., et al., (2020, August). Should Rapid Antigen Tests Be Used As A Screening Tool for COVID-19? Asia Pacific Center for Evidence-Based Healthcare.
Review August 18, 2021	• None identified.	• None identified.	• RADT versus RT-PCR: A major difference between RADTs and RT-PCR is the difference in the analytic sensitivity of the assay. • Sensitivity: Typically, the sensitivity of antigen tests is 30% to 40% lower than for RT-PCR, depending on whether tested subjects were symptomatic or asymptomatic.[46] RADTs are subject to the same considerations as molecular tests with respect to factors that affect clinical sensitivity. These include the quality of sampling and the timing of testing relative to the onset of infection. They have been noted to have diminished performance in the asymptomatic population, which may be related to the lower levels of virus in this group relative to those with symptoms, rather than characteristics of the tests themselves. ○ Lower sensitivity has both disadvantages and benefits. The primary disadvantage is a risk of falsely negative results in people with low viral loads who may be early in their infection, and who go on to spread it to others in subsequent days. In practice, this subpopulation represents just a small fraction of those tested, and risk can be mitigated through serial testing algorithms. ○ There is also a slightly elevated rate of false positives relative to molecular tests, though the rate is dependent on the prevalence	• None identified.	US Centers for Disease Prevention and Control (CDC) and Infectious Disease Society of America (IDSA) (2021). Rapid Testing.

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
			of disease and the proportion of people who are symptomatic. For many commonly used rapid antigen tests, the negative predictive value (e.g., the likelihood someone with a negative test is truly negative for infection) is greater than 98%. ○ A major advantage of these assays is the lower likelihood of detecting residual viral nucleic acid left over from a remote infection in recovered individuals. This reduces the chance of unnecessary initiation of isolation and quarantine precautions and subsequent rounds of testing.		
Review March 23, 2021 [AMSTAR 2/9]	• None identified.	• None identified.	• A rapid review of the literature found no real-world evidence to either support or refute screen testing in preventing LTC home COVID-19 outbreaks. There are several direct harms associated with screen testing, as well as opportunity costs, including exacerbating LTC staffing shortages. • Based on the evidence reviewed and, given the high rates of protection of vaccines against symptomatic and asymptomatic SARS-CoV-2 infection, the potential harms and costs of screen testing among vaccinated LTC home staff likely outweigh the benefits.	• No information identified.	Kain D, Stall NM, Allen V, et al. (2021). Routine Asymptomatic SARS-CoV-2 Screen Testing of Ontario Long-term Care Staff After COVID-19 Vaccination. Science Briefs of the Ontario COVID-19 Science Advisory Table, 2 (15).
Review February 23, 2021	• None identified.	• None identified.	• Symptomatic Testing: Patients with symptoms consistent with COVID-19 who present for care at a hospital or testing centre are the population group that would have the highest likelihood of testing positive. . The purpose of RADTs in this group is to diagnose patients suspected with COVID-19 in cases where molecular testing is not available, or delays in molecular testing results are hampering appropriate patient management and disease control efforts. • Asymptomatic Testing: It is estimated that the likelihood of testing positive in asymptomatic individuals in schools, workplaces, mass gatherings, and travellers would be low (possibly 1–2.5%), unless they are located in a COVID-19 outbreak area. A RADT with 80% sensitivity and 97% will result in NPVs of 99–100% which means that most people testing negative are likely to be true negatives.	• No additional information was identified.	Peeling, R. W., Olliaro, P. L., Boeras, D. I., & Fongwen, N. (2021). Scaling up COVID-19 rapid antigen tests: Promises and challenges. *The Lancet Infectious Diseases*.

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
Review June 15, 2021	• None identified.	• None identified.	• This short review presents the analytical properties of RADTs such as lateral flow immunoassays (LFIAs) in the detection of SARS-CoV-2 in nasopharyngeal swabs.[j]	• Symptomatic: Antigen tests for SARS-CoV-2 show high sensitivity and specificity in cases with high viral loads and should be used up to five days after the onset of the first symptoms of COVID-19. • Asymptomatic: False positive results may be obtained when screening large populations with a low prevalence of COVID-19 infection, while false negative results may happen due to improper specimen collection or insufficient amount of antigen in the specimen.	Bačura, A. S., Dorotić, M., Grošić, L., Džimbeg, M., & Dodig, S. (2021). Current status of the lateral flow immunoassay for the detection of SARS-CoV-2 in nasopharyngeal swabs. *Biochemia Medica, 31* (2).
Single study (Germany) August 20, 2021	• Roche Diagnostics (Rotkreuz, Switzerland); • Lumipulse G SARS-CoV-2 Ag ("CLEIA") from Fujirebio Inc.	• Alpha (B.1.1.7); and • Beta (B.1.351).	• Purpose: The study evaluated PCR-positive (n = 107) and PCR-negative (n = 303) respiratory swabs from asymptomatic and symptomatic patients at the end of the second pandemic wave in Germany (February–March 2021) as well as clinical isolates EU1 (B.1.117), variant of concern (VOC) Alpha (B.1.1.7), or Beta (B.1.351), which had been expanded in a biosafety level three laboratory. • Results: Automated, quantitative SARS-CoV-2 Ag tests show variable performance and are not necessarily superior to a standard point-of-care test (POCT).	• Sensitivity: In this study cohort of hospitalized patients, the clinical sensitivities of tests were low, ranging from 17.76 to 52.34%, and analytical sensitivities ranged from 420,000 to 25,000,000 Geq/ml.	Osterman, A., Iglhaut, M., Lehner, A. et al. (2021). Comparison of four commercial, automated antigen tests to detect SARS-CoV-2 variants of concern. *Medical Microbiology and Immunology*.

[j] Lateral flow immunoassay is a method that combines thin-layer chromatography and indirect immunochemical sandwich method and allows the detection of a specific SARS-CoV-2 antigen in nasopharyngeal swabs. Swab specimens should be adequately collected and tested as soon as possible. Users should pay attention to quality control and possible interferences (Bačura et al., 2021).

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
	(Tokyo, Japan); • LIAISON® SARS-CoV-2 Ag ("CLIA") assay from DiaSorin S.p.A. (Saluggia, Italy);and • Elecsys SARS-CoV-2 Antigen ("ECLIA") assay from Roche Diagnostics GmbH (Mannheim, Germany).		• Implications: The efficacy of any alternative testing strategies to complement nucleic acid-based assays must be carefully evaluated by independent laboratories prior to widespread implementation.		
Single study (Spain) June 9, 2021	• Roche SARS-CoV-2 Rapid Antigen Test.	• None identified.	• Asymptomatic Testing: Roche SARS-CoV-2 Rapid Antigen Test was performed on 2,542 asymptomatic adults in a community with a SARS-CoV-2 incidence of 1.93%. • Implications: This study suggests that rapid antigen tests are less effective in asymptomatic population, when compared with RT-PCR. Further studies are needed to evaluate different options to improve screenings based on rapid antigen test, such as the use of clinical questionnaires to select higher risk-participants, the confirmation of negative results with RT-PCR or the use of repetitive sequential testing.	• Sensitivity: The test showed a sensitivity of 71.43% (CI 95%: 56.74 – 83.42). Test sensitivity was related to viral load, with higher sensitivity in RT-PCR cycle threshold (Ct) values under 25 (93.75%, CI 95%: 71.96 – 98.93), that dropped to 29.41% (CI 95%: 10.31- 55.96) in RT-PCR Ct values above 25. • Specificity: It had a specificity of 99.68% (CI 95%: 99.37 –	Fernandez-Montero, A., Argemi, J., Rodríguez, J. A., Ariño, A. H., & Moreno-Galarraga, L. (2021). Validation of a rapid antigen test as a screening tool for SARS-CoV-2 infection in asymptomatic populations: Sensitivity, specificity, and predictive values. *EclinicalMedicine*, 100954.

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
				99.86). Positive Predictive Value was 81.4 (CI 95% 66.6 – 91.61) and Negative Predictive Value was 99.44 (CI 95% 99.06 – 99.69).	
Single study (UK) June 30, 2021	• Innova Rapid SARS-CoV-2 Antigen Test • Spring Healthcare SARS-CoV-2 Antigen Rapid Test Cassette • E25Bio Rapid Diagnostic Test • Encode SARS-CoV-2 Antigen Rapid Test Device, • SureScreen COVID-19 Rapid Antigen Test Cassette • SureScreen COVID-19 Rapid Fluorescence Antigen Test	• Alpha	• This comprehensive comparison of antigen LFDs and virus infectivity found a clear relationship between cycle threshold (Ct) values, quantitative culture of infectious virus, and antigen LFD positivity in clinical samples. The data support regular testing of target groups with LFDs to supplement the current PCR testing capacity, which would help to rapidly identify infected individuals in situations in which they would otherwise go undetected.	• Specificity: All LFDs showed high specificity (≥98·0%), except for the E25Bio test (86.0% [95% CI 77.9–99.9]), and most tests reliably detected 50 PFU/test (equivalent SARS-CoV-2 N gene Ct value of 23·7, or RNA copy number of 3 × 106/mL). • Sensitivity: Sensitivities of the LFDs on clinical samples ranged from 65.0% (55.2–73.6) to 89.0% (81.4–93.8). These sensitivities increased to greater than 90% for samples with Ct values of lower than 25 for all tests except the SureScreen fluorescence test. ○ Test performance (assessed for Innova and SureScreen-V) was not affected when reassessed on swabs positive for the UK variant B.1.1.7.	Pickering, S., Batra, R., Merrick, B., Snell, L. B., Nebbia, G., Douthwaite, S., … & Galão, R. P. (2021). Comparative performance of SARS-CoV-2 lateral flow antigen tests and association with detection of infectious virus in clinical specimens: A single-centre laboratory evaluation study. *The Lancet Microbe, 2* (9), e461-e471.

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
Single study (preprint) June 26, 2021	• NADAL®. • Panbio™. • MEDsan®.	• Alpha.	• Method: Three RADTs were evaluated compared to quantitative reverse transcription polymerase chain reaction (RT-qPCR) in 5,068 oropharyngeal swabs for detection of SARS-CoV-2 in a hospital setting. The data collection period ranged from November 12, 2020 to February 28, 2021. • Implications: RADT are a reliable method to diagnose SARS-CoV-2 infection in persons with high viral load. RDT are a valuable addition to RT-qPCR testing, as they reliably detect infectious persons with high viral loads before RT-qPCR results are available.[47]	• Sensitivity: The sensitivity of RADT compared to RT-qPCR was 42.57% (95% CI 33.38%–52.31%). Sensitivity declined with decreasing viral load from 100% in samples with a deduced viral load of ≥108 SARS-CoV-2 RNA copies per ml to 8.82% in samples with a viral load lower than 104 SARS-CoV-2 RNA copies per ml. • Specificity: The specificity was 99.68% (95% CI 99.48%–99.80%). • Variant: No significant differences in sensitivity or specificity could be observed between samples with and without variant B.1.1.7. • The NPV in the study cohort was 98.84%; the PPV in persons with typical COVID-19 symptoms was 97.37%, and 28.57% in persons without or with atypical symptoms.	Wagenhäuser, I., Knies, K., Rauschenberger, V., Eisenmann, M., McDonogh, M., Petri, N., … & Krone, M. (2021). Clinical performance evaluation of SARS-CoV-2 rapid antigen testing in point of care usage in comparison to RT-qPCR. *EBioMedicine*.

Single study August 18, 2021	• Panbio-COVID-19 Ag Rapid Test Device.	• No information identified.	• Overview: We evaluated the diagnostic performance of the Panbio-COVID-19 Ag Rapid Test Device (P-RDT) in symptomatic and asymptomatic children (0 to 16 years old); each had two nasopharyngeal swabs for reverse transcription-PCR (RT-PCR) and P-RDT. A total of 822 participants completed the study, of which 533 (64.9%) were symptomatic. • Implications for Children: It would seem very unlikely that children are unnecessarily sent into quarantine, which is important from a public health perspective. The World Health Organization RDT target product profile cut-offs of ≥80% for sensitivity and ≥97% for specificity were achieved for specificity but not for sensitivity. The relatively low sensitivity of the P-RDT is in line with previous data showing an assay sensitivity of 45 to 78% among symptomatic children and confirms that the assay sensitivity is lower than that in symptomatic adults in whom the largest studies report sensitivity between 67 and 92%.	• Sensitivity: The major finding of this study is an overall suboptimal 66% sensitivity of the assay, ranging between 43% and 73% in asymptomatic and symptomatic children. However, among symptomatic children with high viral load (VL), the assay's sensitivity seemed only marginally lower than symptomatic adults with high VL. ○ The suboptimal sensitivity of the assay in children is most likely explained by the increasingly recognized evidence that children have lower SARS-CoV-2 VLs than adults. Another possible explanation for the lower sensitivity could be sampling bias related to the technical challenge of the NPS procedure in children, given that the swab for the P-RDT testing was the second one to be performed. • Specificity: Specificity was 100% regardless	L'Huillier, A., Lacour, M., Sadiku, D., Gadiri, M. A., De Siebenthal, L., Schibler, M., … & Lacroix, L. (2021). Diagnostic Accuracy of SARS-CoV-2 rapid antigen detection testing in symptomatic and asymptomatic children in the clinical setting. *Journal of Clinical Microbiology, 59 (9).*

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
				of the presence or absence of symptoms. • Variants: False-negative RDT results have also been observed in adult RDT studies, even though less frequently, and are unlikely to be caused by SARS-CoV-2 variants. Indeed, no mutation in the N gene possibly causing false-negative RDTs in circulating SARS-CoV-2 variants have been identified and, so far, all variants are detected with RDTs with comparable sensitivity to earlier circulating variants.	
Single study August 2021	• Quidel sofia SARS antigen FIA test (Sofia 2).	• Whole genome sequencing of the specimen uncovered two mutations, T205I and D399N.[k]	• Results: All six SARS-CoV-2 positive clinical specimens available in our laboratory with a D399N nucleocapsid mutation and CT < 31 were not detected by the Sofia 2 but detected by the Abbott BinaxNOW COVID-19 Ag Card, while clinical specimens with the T205I mutation were detected by both assays.	• Sensitivity: The Sofia 2 had a 1000-fold lower sensitivity for recombinant proteins containing the D399N nucleocapsid mutation.	Bourassa, L., Perchetti, G. A., Phung, Q., Lin, M. J., Mills, M. G., Roychoudhury, P., … & Greninger, A. L. (2021). A SARS-CoV-2 nucleocapsid variant that affects antigen test performance. *Journal of Clinical Virology*, 104900.

[k] The D399N mutation is uncommon to date and present in 0.02% global SARS-CoV-2 genomes (Bourassa et al., 2021).

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
Single study July 30, 2021	• LIAISON® XL.	• 20I/501Y.V1 ('UK' variant). • 20H/501Y.V2 ('South African' variant).	• Symptomatic and Asymptomatic Samples: The study involved 378 nasopharyngeal samples including 46 swabs positive for SARS-CoV-2 by RT-PCR. These samples came from asymptomatic (n=99, 26.2%) or symptomatic people (n=279, 73.8%), at different times from symptom onset. The samples were analyzed on LIAISON® XL. • Implications: The LIAISON® SARS-CoV-2 Ag test may be a useful tool for COVID-19 diagnosis, especially during the first four days of symptoms.	• Specificity: The overall specificity was 99.4% (CI95% [98.6–100]). The negative predictive value reached 100% in asymptomatic people. • Sensitivity: Among the 46 positive samples, the overall sensitivity was 84.8% (CI95% [74.4–95.2]), reached 91.9% (CI95% [83.1–100]) in the first four days after symptoms onset and was 100% for Ct values ≤25.Antigen was not detected in samples with Ct values >25. • Variants: Similar results were observed on nasopharyngeal swabs coming from patients infected with the 20I/501Y.V1 variant or the 20H/501Y.V2 variant.	Hartard, C., Berger, S., Josse, T., Schvoerer, E., & Jeulin, H. (2021). Performance Evaluation of an automated SARS-CoV-2 Ag test for the diagnosis of COVID-19 infection on nasopharyngeal swabs. *Clinical Chemistry and Laboratory Medicine (CCLM)*.

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
Single study July 1, 2021	• No information identified.	• 202012/01.	• Method: The study was conducted on 4,266 naso-oropharyngeal swabs. Samples were subjected to antigen RT-PCR tests for the detection of SARS-CoV-2, and related variants. • Implications: Molecular and antigen tests should be evaluated regarding the prevalence of the area. In case of low prevalence, antigen testing can be employed as a first-line screening for the timely identification of affected individuals with high viral load, also if carriers of SARS-CoV-2 variants.	• Results: Antigen test identified positive samples with high viral load by high pg/mL levels. Reduced concordance was shown as viral load decreases. ○ *Variants*: Antigen testing identified variant carriers according to their viral load.	Caputo, V., Bax, C., Colantoni, L., Peconi, C., Termine, A., Fabrizio, C., … & Giardina, E. (2021). Comparative of antigen and molecular tests for the detection of Sars-CoV-2 and related variants: a study on 4266 samples. *International Journal of Infectious Diseases, 108, 187-189.*
Single study July 16, 2021	• Abbott BinaxNOW.	• Alpha, Beta, Gamma, Delta (B.1.617.2); and • B.1.2 (a non-VOC sub-strain of B.1).	• Overall, these data indicate that while BinaxNOW accurately detects the new viral variants, as rapid COVID-19 tests are used in the home, their already lower sensitivities compared to RT-PCR may decrease even more due to user error.	• Sensitivity: While BinaxNOW detected the highly infectious variants, test sensitivity decreased with decreasing viral loads. ○ BinaxNOW sensitivity trended lower when devices were performed by patients/caregivers themselves compared to trained clinical staff, despite universally high usability assessments following self/caregiver-administration among different age groups.	Frediani, J. K., Levy, J. M., Rao, A., Bassit, L., Figueroa, J., Vos, M. B., … & Lam, W. A. (2021). Multidisciplinary assessment of the Abbott BinaxNOW SARS-CoV-2 point-of-care antigen test in the context of emerging viral variants and self-administration. *Scientific Reports*, *11* (1), 1-9.

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
Single study April 5, 2021	• Abbott BinaxNOW	• None identified.	• Method: Study conducted rapid antigen (BinaxNOW™) and oral fluid RT-PCR (Curative Labs) tests on children presenting at a walk-up testing site in Los Angeles County from November 25 to December 9, 2020. • Symptomatic versus Asymptomatic Children: Positive concordance was higher among symptomatic children (64.4%; 95% CI: 53.4% to 74.4%) compared to asymptomatic children (51.1%; 95% CI: 42.5% to 59.7%). • Implications: RADT can successfully identify most COVID infections in children with viral load levels likely to be infectious. Serial rapid testing may help compensate for limited sensitivity in early infection.	• RT-PCR versus RADT: 226 children tested positive on RT-PCR; 127 children or 56.2% (95% CI: 49.5% to 62.8%) tested positive on RADT. • Positive concordance was negatively associated with Ct values and was 93.8% (95% CI: 69.8% to 99.8%) for children with Ct values less than or equal to 25. 548 children tested negative on RT-PCR; 539 or 98.4% (95% CI: 96.9% to 99.2%) of these also tested negative on the rapid antigen test. Negative concordance was higher among asymptomatic children.	Sood, N., Shetgiri, R., Rodriguez, A., Jimenez, D., Treminino, S., Daflos, A., & Simon, P. (2021). Evaluation of the Abbott BinaxNOW antigen test for SARS-CoV-2 infection in children: Implications for screening in a school setting. *Plos One,16* (4), e0249710.

Type of Evidence	Brand(s)	Variant(s)	Description	Details	Reference
Single study July 1, 2021	• PANBIO COVID-19 Ag RAD (Abbott) test.	• None identified.	• The objective of this study was to determine the performance of the PANBIO COVID-19 Ag RAD (Abbott) test. It was conducted in a tertiary Children's Hospital and included individuals aged ≤16 years with COVID-19-related symptoms or epidemiological criteria for COVID-19. Two nasopharyngeal samples were collected to perform the PANBIO RAD test and RT-PCR. Of 744 children included, 51 (6.86%) had a positive RT-PCR result. The RAD test detected 42 of 51 PCR-positive children while there were no false-positive results.	• The overall sensitivity and specificity were 82.35% (95% CI, 71.9%-92.8%) and 100%, respectively. Sensitivity was >95% in symptomatic children. The assay performed poorly in asymptomatically infected children. • In agreement with previous studies in adults, the PANBIO RAD test can be useful in screening for COVID-19 in children admitted with symptoms suggestive of the disease, especially in the first days of the illness.[48]	Eleftheriou, I., Dasoula, F., Dimopoulou, D., Lebessi, E., Serafi, E., Spyridis, N., & Tsolia, M. Real-life evaluation of a COVID-19 rapid antigen detection test in hospitalized children. *Journal of Medical Virology (10)*, 6040-6044.
Single study August 27, 2021	• No information identified.	• No information identified.	• Purpose: The study included 257 affiliates of three coworking laboratories in Cambridge and Boston, Massachusetts. The prevalence of COVID-19 during the study was between less than 1% and 8%. Individuals self-collected nasal swab specimens twice weekly at home during a six-month period. Direct antigen rapid tests (DART) were performed at home, and the findings were compared with laboratory qRT-PCR tests • Implications for Asymptomatic Testing: Most of the positive participants reported that they did not recognize symptoms of COVID-19 until they received a positive result. Policies that rely on self-reported symptoms miss or delay detection and allow viral spread within communities. Frequent at-home testing with DART allows infected individuals to be identified and quarantined immediately. Such surveillance can prevent viral transmission in in-person work environments or other social settings.	• Sensitivity: The sensitivity of DART within days 0 to 12 of symptom onset was 78.9% (60 of 76 swabs; 95% CI, 69.1%-88.8%). • Specificity: The specificity of DART was 97.1% (2791 of 2875 swabs; 95% CI, 96.3%-97.8%).	Harmon, A., Chang, C., Salcedo, N., Sena, B., Herrera, B. B., Bosch, I., & Holberger, L. E. (2021). Validation of an at-home direct antigen rapid test for COVID-19. *JAMA Network Open, 4* (8), e2126931-e2126931.

Table 3: Rapid Antigen Detection Tests for Diagnostic Testing of SARS-CoV-2 Variants (without PCR Confirmation) in Symptomatic and Asymptomatic Individuals across Jurisdictions

Jurisdiction	RADT Brand	Variant Focus	Population/Setting	Description of Policy
United States (September 2021)	• Various with emergency-use authorization from the Food and Drug Administration (e.g., Abbott BinaxNOW, Ellume COVID-19 Home, QuickVue).	• Various.[49]	• Anyone, purchased online or at pharmacy.[50]	• President Biden's COVID-19 Action Plan implements a six-pronged, comprehensive national strategy to combat variants of COVID-19, one of which is increasing the amount of testing. ○ Accelerate the production of rapid COVID-19 tests, including at-home tests, and continue to ensure that manufacturers prioritize creating these products to prevent the spread of COVID-19 and its variants. Using authorities of the Defense Production Act and through the procurement of nearly CAD $2.4 billion in rapid POC and over-the-counter at-home COVID tests – 280 million tests in all – from multiple COVID-19 test manufacturers, the Administration will ensure a broad, sustained industrial capacity for COVID-19 test manufacturing.[l] These tests will be available to support a range of needs, including long-term care facilities, community testing sites, critical infrastructure, shelters serving individuals experiencing homelessness, prisons and jails, and other vulnerable populations and congregate settings. ○ To improve access to rapid tests for all consumers, top retailers that sell at-home, rapid COVID-19 tests (e.g., Walmart, Amazon, and Kroger) will offer to sell those tests at-cost for the next three months. This means that Americans will be able to buy these tests at their local retailers or online for up to 35% less. The Administration has also taken action so that Medicaid must cover at-home tests for free for beneficiaries, and that states should ensure that any tools they use to manage at-home testing do not establish arbitrary barriers for people seeking care.[51]
United Kingdom	• Innova Lateral Flow Device (Biotime SARS-CoV-2 Lateral Flow Antigen	• Alpha, Delta ○ Findings from three studies (two published by the government and one	• Only for asymptomatic individuals.[54] • Tests can be mailed to homes,	• Free test that provides a quick result using a device similar to a pregnancy test.[56] The test involves rubbing a long cotton bud (swab) over the tonsils and inside the nose, or inside the nose only.[57] • Individuals are encouraged to do a rapid test twice a week (every three to four days) to check if they have the virus.

[l] The document reported a figure of USD $2 billion. The Canadian Dollar (CAD) amount was calculated using Purchasing Power Parities (PPPs) as published by the Organisation for Economic Co-operation and Development (OECD) for 2020 (1 United States dollar [USD] = 1.206 CAD). PPPs are the rates of currency conversion that eliminate the differences in price levels between countries (OECD, 2021).

Jurisdiction	RADT Brand	Variant Focus	Population/Setting	Description of Policy
	Device).[m]	by Liverpool University) on the real-world use of LFDs have confirmed their effectiveness under a variety of conditions (e.g., against variants of concern, patients with low/high viral loads, mass testing campaigns, hands of inexperienced users, different types of swabs), demonstrating their reliability and adaptability.[52] ○ Routine post-market surveillance shows there is no significant difference in the Innova LFDs' abilities to detect the Delta and Alpha variants.[53]	picked up at a pharmacy or other collection point, or conducted at test sites, schools, universities, or employer sites.[55]	● If there is a positive result or the test sample could not be read, individuals should do a PCR test.[58] ● Test results should be reported online within 24 hours of being tested.[59]
Italy (Apr 28, 2021)	● RADTs (no specific brand identified).[60]	● Various, including Alpha and Gamma.[61]	● Cases of close contacts of a confirmed case without symptoms and without others at risk in their household; for people displaying	● RADTs, when performed on close contacts of positive subjects or in cluster areas with a high concentration of positive cases, will be sufficient to diagnose a patient as positive to COVID-19, without further testing. ● On February 15, 2021, the Ministry of Health updated the indications regarding the use of RADTs, given the circulation of new variants of the virus. Specifically, the new variants should still be detected by antigen tests; however, the situation will have to be closely

[m] Xiamen Biotime is manufacturer of the SARS-CoV-2 Lateral Flow Antigen Test as used in the Innova SARS-CoV-2 Lateral Flow Antigen Test Kit for professional use and Department of Health and Social Care's COVID-19 Self-Test Kit for 'home' self-test use (Stockbridge et al., July 7, 2021).

Jurisdiction	RADT Brand	Variant Focus	Population/Setting	Description of Policy
			milder symptoms; and for people arriving from countries at risk. • Rapid tests are also the first choice in community screenings, and for those who voluntarily undergo the test for personal reasons, travel, or work needs.[62]	monitored. No further information was identified.[63]
Australia (Sept 8, 2021)	• 14 different RADT kits manufactured by various countries (e.g., Germany, US, Singapore).[64]	• Various, including Delta.[65]	• RADTs are used for symptomatic patients by trained health professionals or laboratory scientists.[66] • RADTs are not intended for home testing. However, the Therapeutic Goods Administration (TGA) is progressing work that would allow the provision of these tests in the future. • Some states (e.g., Western Australia, South	• RADTs are generally best performed within the first five to seven days from the time symptoms first appear. Negative results, and some positive results, may require further testing by a nucleic acid test to confirm if a patient is infected with the SARS-CoV-2 virus.[68] • The TGA is undertaking a post-market review of all PoC and laboratory tests on the Australian Register of Therapeutic Goods (ARTG) that are intended to identify individuals with COVID-19. The review verifies whether these tests can accurately detect emerging genetic variants of the SARS-CoV-2 virus; and complements the TGA's ongoing review of the overall performance of PoC tests. • The TGA is monitoring the emerging variants of SARS-CoV-2 with at least 5% prevalence in the global population (i.e., mutations that occur in at least 5% of each viral variant) and will keep monitoring these variants as they continue to mutate. • The manufacturers of RADTs have provided the TGA with study data to validate the performance of the kits, including in-silico analysis, recombinant protein studies, live virus studies, and inactivated virus studies against the Alpha, Beta, Gamma, Delta, Delta Plus, Kappa, Epsilon, Eta, Iota, Zeta, Theta and Lambda variants. • As of August 31, 2021, there are 14 RADT test kits that have evidence to support their continued performance with various variants. Thirteen of the 14 RADTs have evidence of performance against the Delta

Jurisdiction	RADT Brand	Variant Focus	Population/Setting	Description of Policy
			Australia) have prohibited or restricted use of RADTs as an acute illness diagnostic tool for COVID-19.[67]	variant. ● The review is ongoing and information about the performance of each RADT against the variants will be published here as it becomes available.[69]

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