In brief

Rapid antigen testing

18 August 2021

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- Rapid antigen tests are one of four main types of COVID-19 tests.¹
- The <u>other test types</u> are nucleic acid amplification tests (PCR), <u>rapid molecular tests</u> (e.g. Xpert Xpress) and antibody tests.^{1, 2}
- The strengths of rapid antigen tests³ are:
 - Timeliness, with most taking 15-30 minutes from test to result
 - Sample type used (usually a nasal swab or saliva) which are more acceptable to people
 - No requirement for specialist equipment (although some <u>use immunofluorescence</u>)⁴
 - o Relatively low cost, with most costing \$5-\$20 per test.⁵
- Rapid antigen tests have <u>lower sensitivity and specificity</u> compared with gold standard PCR tests.¹
- Current Australian advice is that rapid antigen tests are not suitable for <u>diagnostic purposes</u> due to high rates of false positives and false negatives when used as a single one-off test.⁶
- However, rapid antigen tests have value as a <u>screening step</u> followed by confirmatory goldstandard PCR testing – particularly in outbreaks where there is <u>high local disease prevalence</u> (such as <u>currently in Sydney</u>).⁷⁻⁹
- Issues with false positive and false negative test can be addressed by repeat testing.¹⁰
- Rapid tests can play an important role in <u>expanding testing capacity</u> for example in emergency departments, schools and certain industries.¹¹
- Rapid testing is used differently across jurisdictions, for example a rapid, regular community testing program (lateral flow) for asymptomatic individuals was rolled out <u>in England.¹²</u>
- <u>Self-testing</u> is currently prohibited in Australia.¹³
- In Australia, the <u>Royal College of Pathologists of Australasia</u> remains concerned over the uncontrolled use of rapid antigen tests, however recognises that in localised outbreaks use of these tests for surveillance alongside mainstream testing may be appropriate.¹⁴
- The Therapeutics Good Administration (TGA) recommends antigen tests should be <u>performed</u> by health professionals in accordance with the manufacturer's instructions.² <u>Training is required</u> in the correct use of the device and interpretation of results.⁹
- Other options to increase testing capacity include <u>sample pooling</u>.¹⁵





In brief documents are not an exhaustive list of publications but aim to provide an overview of what is already known about a specific topic. This brief has not been peer-reviewed and should not be a substitute for individual clinical judgement, nor is it an endorsed position of NSW Health.

References

- 1. Dinnes J, Deeks JJ, Berhane S, et al. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. Cochrane Database Syst Rev. 2021(3):1-409. DOI: 10.1002/14651858.CD013705.pub2
- 2. Therapeutic Goods Adminstration. COVID-19 testing in Australia information for health professionals [Internet]. Australia: Therapeutic Goods Adminstration, Department of Health, Australian Government; 4 December 2020 [cited 12 August 2021]. Available from: https://www.tga.gov.au/covid-19-testing-australia-information-health-professionals
- Centers for Disease Control and Prevention. Interim guidance for antigen testing for SARS-CoV-2 [Internet]. United States: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases, Centers for Disease Control and Prevention; 14 June 2021 [cited 12 August 2021]. Available from: <u>https://www.cdc.gov/coronavirus/2019ncov/lab/resources/antigen-tests-guidelines.html</u>
- 4. Wang D, He S, Wang X, et al. Rapid lateral flow immunoassay for the fluorescence detection of SARS-CoV-2 RNA. Nat Biomed Eng. 2020;4(12):1150-8. DOI: 10.1038/s41551-020-00655-z
- 5. Williamson D. What role should antigen tests play in Australia's COVID response? [Internet]. Australia: newsGP-RACGP; 04 Aug 2021 [cited 12 August 2021]. Available from: https://www1.racgp.org.au/newsgp/clinical/what-role-should-antigen-tests-play-in-australia-s
- 6. The Royal College of Pathologists of Australasia. COVID-19 antigen and point of care testing [Internet]. Australia: The Royal College of Pathologists of Australasia (RCPA); August 2021 [cited 12 August 2021]. Available from: <u>https://www.rcpa.edu.au/Library/College-Policies/Position-Statements/COVID-19-Antigen-and-Point-of-Care-Testing</u>
- Yokota I, Shane PY, Teshima T. Logistic advantage of two-step screening strategy for SARS-CoV-2 at airport quarantine. Travel Med Infect Dis. 2021 Jun 23;43:1-7. DOI: 10.1016/j.tmaid.2021.102127
- 8. Schwartz KL, McGeer AJ, Bogoch II. Rapid antigen screening of asymptomatic people as a public health tool to combat COVID-19. CMAJ. 2021;193(13):1-4. DOI: 10.1503/cmaj.210100
- Therapeutic Goods Adminstration. Q&As Conditions of supply for rapid antigen tests [Internet]. Australia: Therapeutic Goods Adminstration, Department of Health, Australian Government; 10 August 2021 [cited 12 August 2021]. Available from: <u>https://www.tga.gov.au/qas-conditions-supply-rapid-antigen-tests</u>
- 10. Abbasi J. Antigen testing every 3 days is highly sensitive for SARS-CoV-2. JAMA. 2021;326(6):473. DOI: 10.1001/jama.2021.12620
- 11. Menchinelli G, De Angelis G, Cacaci M, et al. SARS-CoV-2 antigen detection to expand testing capacity for COVID-19: results from a hospital emergency department testing site. Diagnostics. 2021;11(7):1-9. DOI: 10.3390/diagnostics11071211
- 12. Department of Health and Social Care. Asymptomatic testing to be rolled out across the country starting this week [Internet]. United Kingdom: Department of Health and Social Care, GOV.UK; 20 January 2021 [cited 12 August 2021]. Available from: <u>https://www.gov.uk/government/news/asymptomatic-testing-to-be-rolled-out-across-the-country-starting-this-week</u>
- 13. Therapeutic Goods Adminstration. Legal supply of COVID-19 test kits [Internet]. Australia: Therapeutic Goods Adminstration, Department of Health, Australian Government; 19 February 2021 [cited 12 August 2021]. Available from: <u>https://www.tga.gov.au/legal-supply-covid-19-test-kits</u>
- 14. The Royal College of Pathologists of Australasia. Media Releases: RCPA updates advice surrounding rapid antigen tests [Internet]. Australia: The Royal College of Pathologists of Australasia (RCPA); 10 August, 2021 [cited 12 August 2021]. Available from: <u>https://www.rcpa.edu.au/News-and-Media-Releases/Media-Releases</u>
- 15. Wei S, Suryawanshi H, Djandji A, et al. Field-deployable, rapid diagnostic testing of saliva for SARS-CoV-2. Sci Rep. 2021;11(1):1-9. DOI: 10.1038/s41598-021-84792-8

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