

Public Health Laboratory Network – Communicable Diseases Network Australia

Joint Statement on SARS-CoV-2 Rapid Antigen Tests

Revision history

Version	Date published	Revision notes
2.2	25 January 2022	Additional updates following National Cabinet meeting of 5 January 2022.
2.1	16 December 2021	Updated to incorporate Therapeutic Goods Administration changes to rapid antigen self-test restrictions, and advice regarding testing sensitivity in relation to emerging variants.
2.0	11 August 2021	Updated principles, requirements and recommendations for use.
1.0	9 October 2020	Initial document

The Public Health Laboratory Network (PHLN) and Communicable Diseases Network Australia (CDNA) continue to monitor and consider the potential for use of SARS-CoV-2 (the virus that causes COVID-19) rapid antigen tests (RATs) in Australia.

At this time¹, in the context of widespread community transmission, PHLN and CDNA recommend deployment of RATs to enhance and preserve laboratory-based testing capacity. This may be decided at the discretion of the relevant state or territory in line with the [Testing Framework for COVID-19 in Australia](#) (the Testing Framework) and the [COVID-19 CDNA National Guidelines for Public Health Units](#) (the National Guidelines). The Testing Framework describes how RATs may be effectively used to enhance Australia's COVID-19 response, while mitigating associated potential limitations and risks (described below). The National Guidelines outline Australia's national minimum standard for

¹ Update January 2022, version 2.2.

surveillance, laboratory testing, case management and contact management for COVID-19. Further, RAT use should accord with relevant jurisdictional and national laws and regulations.²

Testing for SARS-CoV-2 is central to detecting new and emerging outbreaks. It is also a key pillar in controlling the COVID-19 pandemic. In Australia, nucleic acid amplification (NAA) using reverse transcription polymerase chain reaction (RT-PCR)³ is the current reference standard SARS-CoV-2 diagnostic test. NAA tests are very sensitive and detect viral nucleic acid sequences that are specific to the SARS-CoV-2 virus in a respiratory tract sample.

Currently, as Australia responds to increasing case numbers due to SARS-CoV-2 Omicron variant, laboratory-based NAA testing capacity is overwhelmed in several jurisdictions. In this epidemiological context, laboratory-based NAA should be reserved for testing of symptomatic individuals, especially those at higher risk of severe disease, and asymptomatic people in high and special-risk settings (where a confirmed case has already been identified and transmission is likely). This will assist with maintaining reasonable testing turnaround times (TAT) and ensure an appropriate and timely public health response. Refer to the Testing Framework for more information.

RATs are intended for use at the point-of-care (or near person care) or for self-testing (also known as home tests). Like NAA, RATs require collection of a respiratory tract swab sample, saliva or oral fluid. The time required for sample collection and user acceptability are therefore the same as for NAA. However, in contrast to NAA, the design of these tests is to detect the presence of viral proteins produced by SARS-CoV-2. In doing so, the tests can provide a presumptive positive result for COVID-19 in persons with suspected infection. PHLN and CDNA note that the advantages of rapid antigen testing include:

- ease-of-use testing method
- rapid turnaround from specimen collection to result (15–30 minutes)
- potential lower relative cost to NAA (depending on frequency of use)
- ability to use as a self-test (at home, without supervision) which became available on 1 November 2021
- improved accessibility for populations far removed from pathology laboratories
- with regular testing, enhanced confidence of lower likelihood of being infectious in the community and
- the potential to supplement or conserve laboratory-based NAA capacity.

These advantages are offset by a number of limitations. Currently, there is considerable variability in

² <https://www.tga.gov.au/covid-19-point-care-tests>

³ In this document, RT-PCR also includes transcription mediated amplification (TMA) technology used in some commercial laboratory-based in vitro diagnostic devices. In this context, TMA is equivalent with RT-PCR.

the performance between different RATs, and they are less sensitive compared to the gold standard NAA for the diagnosis of COVID-19. This represents a potential risk in environments with low community transmission where the accuracy of every single test counts. Limitations of RATs are described in detail within the [Limitations of SARS-CoV-2 rapid antigen tests](#) section of this document. It is recommended that these limitations are carefully considered along with the epidemiological context and advantages of RATs.

Please note, in the current surge situation, reserving NAA testing for symptomatic cases and rapid antigen testing for asymptomatic contacts is justified. However, depending on the sensitivity and specificity of the RAT kit used, some RAT-positive results will still represent false-positive results even in a high-prevalence setting. False-negative results will also occur, especially in those without symptoms. In specific cases, state and territory health authorities may therefore choose to require NAA testing on some asymptomatic cases and to confirm some RAT-positives by NAA. For example, specific cases may include:

- Asymptomatic cases where NAA testing may be required:
 - Remote and rural communities with low prevalence to identify cases early
 - High-risk settings (for example, residential aged care facilities) to identify an index case only, determine extent of outbreak.
 - Cases at high-risk of severe disease (for example, immunosuppressed individuals) who may be eligible for monoclonal antibody therapy.
- RAT-positive where confirmatory NAA testing may be required:
 - Cases at high-risk of severe disease (for example, immunosuppressed individuals) who may be eligible for monoclonal antibody therapy.
 - RAT-positive critical workers (for example, healthcare workers) to confirm need for furlough,
 - Initial index case in high-risk settings to confirm an outbreak before triggering an outbreak response plan.

Guidance for implementing a RAT testing program

Principles for use

RATs should be used in accordance with the following principles:

1. RATs may be used for public health investigation where the pre-test probability is high. For example:
 - where a NAA confirmed case has been identified in a closed setting,
 - to rapidly identify an outbreak in a closed setting where there are a number of symptomatic individuals and rapid access to NAA is not available, or
 - where community transmission has been established.
2. Rapid antigen testing may be considered for use where NAA is unavailable or where an extensive delay in result TAT is anticipated.
3. RATs may be used for screening purposes at an interval sufficient to mitigate the reduced sensitivity of the test. This interval is test and prevalence specific, therefore a set interval cannot be applied across all such devices.
4. In low community transmission environments, public health authorities should consider the potential impact:
 - of false negative results from RATs used in outbreak settings, i.e., a small proportion of cases may initially be missed. This may have an adverse impact on outbreak control and public confidence.
 - on public health resources of false positive results from RATs when used without careful integration in the SARS-CoV-2 detection workflow.
5. The decision to use a specific RAT in a given setting may need to be revoked in the event of further reduction in test sensitivity caused by antigenic change in newly emerging variants.
6. The need for genomic sampling strategy that is broadly representative of geographic location, age groups, sex and aligned with the *CDGN, PHLN and CDNA Sampling Strategy for SARS-CoV-2 Genomic Surveillance*. This strategy should include both NAA-confirmed and RAT-positive samples to ensure sampling is representative. For more information, please refer to the [PHLN guidance on laboratory testing for SARS-CoV-2 \(the virus that causes COVID-19\)](#)

Requirements and recommendations for use

When used outside of a research framework, RATs must be used in accordance with the following requirements:

1. RATs selected for use must be included in the [Australian Register of Therapeutic Goods \(ARTG\)](#), and be supplied in accordance with conditions prescribed by the Therapeutic Goods

Administration (TGA).

2. RATs used at the point-of-care must be used in accordance with [the National Pathology Accreditation Advisory Council Guidelines for Point of Care Testing](#).⁴
3. Rapid antigen testing should be undertaken in accordance with any public health orders and/or regulations of the jurisdiction where they are used.
4. RATs must be used in strict accordance with the manufacturer's instructions for use (IFU). Currently, approved RATs variously require the collection of nasopharyngeal, oropharyngeal, nasal, saliva or oral fluid samples. The sample type(s) which each test has been validated for is described in the IFU. Use outside these instructions may compromise the test result and breach TGA regulations in relation to supply and use of these tests.
5. Where a person tests positive to a RAT, it is recommended that
 - a. The person be immediately isolated, and
 - b. Subsequent public health action aligns with the 'test' 'trace', 'isolate' and 'quarantine' (TTIQ) framework and jurisdictional public health measures, aimed at reducing community transmission of SARS-CoV-2. Refer to the National Guidelines for minimum testing requirements.
6. Negative results from a RAT must be considered in the context of an individual's clinical history, clinical observation, and epidemiological information. NAA should always be the first choice for testing a symptomatic individual, however where a symptomatic person presents a negative RAT result, it is recommended that they have a follow-up NAA test, where possible. Persons with negative results should not be assumed to be non-infectious and a negative result must not be used to negate the need for other appropriate interventions (such as mask-wearing and physical distancing).
7. Employers intending to deploy RATs must first consider Australian validation data from the use of the specific test. Employers without in-house expertise should consult with relevant health experts to develop targeted workplace screening approaches, including staff testing program. Organisation enrolment in a RAT quality assurance program is strongly recommended.
8. Employers intending to deploy formal RAT screening programs should seek advice from their jurisdictional public health authority on whether there is a need to report test numbers periodically. It is recommended that this report include the number of tests conducted (including a breakdown of positive and negative results), and the date and location of collection to help predict with greater confidence the prevalence of the virus in the community. It is also recommended that testing numbers be reported by the facility at a frequency to be determined by the jurisdictional public health authority.
9. It is recommended that public health authorities report aggregated testing data received to the

⁴ Noting operating staff training procedures and quality management expectations.

Australian Government Department of Health, to inform pandemic response activities and ensure the COVID-19 testing strategy remains appropriate to the Australian context. The reporting of false negative and false positive results to the TGA through the Medical Device [Incident Reporting and Investigation Scheme](#) (IRIS) is also encouraged.

10. In the context of emerging variants of concern (VoC), it is possible that emerging VoC may have sufficient genomic changes in key areas to make diagnostic escape possible. During a period of uncertainty when a new VoC emerges, caution should be applied to the use of rapid antigen testing technology until assurance has been provided by the TGA that the diagnostic accuracy of the test has not been impacted.

Guidance for self-testing

Rapid antigen self-tests (home use tests) are tests that can be used unsupervised at home without the involvement of a health practitioner. A person collects their own sample, or a sample from a family member, performs the test and interprets the results by themselves. The TGA has approved rapid antigen self-tests for supply in Australia from 1 November 2021.

It is important that for any positive rapid antigen self-test result, you immediately isolate and contact the appropriate state/territory health department for any local requirements. If you have symptoms but get a negative result with a self-test you should also seek to have a PCR test, or repeat the RAT after 24 hours. While not a requirement, you may wish to isolate if you have received a negative RAT result but remain symptomatic with COVID-19 compatible symptoms.

A list of all COVID-19 rapid antigen self-tests (home use tests) that are approved for supply in Australia is available on the TGA website along with the manufacturer's instructions for how to use the test. This list is regularly updated as new tests are approved or if tests are cancelled or withdrawn.

It is important to note that in community settings where there are low rates of COVID-19, there is a high risk of false positive and false negative results.

Settings

Testing for SARS-CoV-2 remains important for controlling the COVID-19 pandemic in Australia. Testing for COVID-19 must accord with epidemiological and clinical criteria in the National Guidelines. Unless otherwise directed by public health authorities, the recommended approach to testing for COVID-19 focuses on testing people with clinically compatible symptoms described by the National Guidelines.

Supplementary and novel testing technologies continue to emerge in both the international and domestic markets. A summary of these can be found in the [Testing Framework for COVID-19 in Australia](#). As a result, PHLN and CDNA continue to monitor emerging SARS-CoV-2 testing technologies and their potential application in the Australian context, including RAT.

Based on current evidence, PHLN and CDNA advise that RATs may be appropriate for use in settings where:

- NAA is unavailable, or prolonged turnaround times preclude clinical utility (for example in the context of high community transmission).
- To support outbreak investigations (for example, in closed or semi-closed groups like schools, care homes, workplaces).
- To monitor trends in COVID-19 rates in communities, and particularly among essential workers and health workers during outbreaks or in regions of widespread community transmission.
- Testing of asymptomatic close-contacts of confirmed cases.

Further information on rapid SARS-CoV-2 antigen testing is available in the [PHLN guidance on laboratory testing for SARS-CoV-2](#) and the [TGA website](#). Additional information on the use of COVID-19 point-of-care tests in the Australian setting is available on the [National Pathology Accreditation Advisory Council website](#).

Limit available on RS-CoV-2 rapid antigen tests

RATs are generally less sensitive and may be less specific compared to NAA. This is based on published evidence. Most current RATs claim that maximal sensitivity is achieved when testing symptomatic individuals within the first 5–7 days of the onset of symptoms. While there is emerging literature on testing performance of asymptomatic individuals⁵, their clinical utility for use as a screening test in low prevalence settings has not been established⁶. This represents a potential risk in low case environments where the accuracy of every single test counts. Where the prevalence of COVID-19 or pre-test probability is low, there is also a risk of false positive results. Misinterpretation of results can have significant public health consequences, including inappropriate management of the individual and their contacts. In addition, all viruses, including SARS-CoV-2, change over time as part of their natural evolution. This change may impact on the diagnostic accuracy of the test. However, specific use cases may be developed for RATs that incorporate mitigation of limitations, and anticipated risk. For example, a lower testing performance may be mitigated by frequent and repeated use in the same individual. An appropriate interval for testing depends on the test selected. The effect of prior vaccination or infection on RAT performance is unknown. For more information, please see the Testing Framework.

Limitations of RATs may be summarised as:

- lower sensitivity and specificity than NAA, leading to false negative and false positive results

⁵ García-Fiñana, Marta, et al. "Performance of the Innova SARS-CoV-2 antigen rapid lateral flow test in the Liverpool asymptomatic testing pilot: population based cohort study." *BMJ* 374 (2021).

⁶ Taylor-Phillips, Sian, and Jacqueline Dinnes. "Asymptomatic rapid testing for SARS-CoV-2." *BMJ* (2021).

- lack of data recording, data integrity, data management and reporting capability for most assays
- notification mechanism to health authorities not provided and
- possible changes in test sensitivity due to emerging SARS-CoV-2 variants.

Use of RATs outside of a laboratory or clinical environment may result in:

- failure to notify public health of a presumptive positive result
- failure to consider the need for NAA testing if symptomatic
- incomplete data capture and reporting of presumptive positive and negative results to public health and
- inappropriate communication of unconfirmed RAT results.

Finally, when making procurement decisions, users and purchasers should note the difference between analytical sensitivity and clinical sensitivity when assessing and comparing the performance characteristics of a RAT. Analytical sensitivity is predominantly measured by in vitro laboratory studies designed to assess the test's limits of detecting SARS-CoV-2. In contrast, clinical sensitivity (the 'real-world' performance of the test) depends on several factors, including:

- sampling (for example, healthcare-practitioner collected versus self-collected)
- days post-symptom onset
- adequacy of test procedure, and
- the kinetics of viral shedding, depending on variant and vaccination status.

The performance of a RAT in laboratory-based studies does not link directly to the clinical performance of a RAT, given the variable factors associated with their use.