



# *The use of Rapid Antigen Testing in Aboriginal and Torres Strait Islander Communities in Queensland*

## *Interim Guidance*

*5 January 2021*

In Australia, reverse-transcription polymerase chain reaction (RT-PCR) using a throat and bilateral deep nasal (or nasopharyngeal) swab is the gold standard diagnostic test for confirming SARS-CoV-2 (the virus that causes COVID-19). It is recommended that anyone with symptoms compatible with COVID-19 is tested using PCR.

However, during outbreaks or periods of higher community transmission of COVID-19, **Rapid Antigen Tests** may be used.

Rapid antigen tests (RATs) can detect the COVID-19 virus early in the infection, sometimes before symptoms appear. Because they provide results on the spot, rapid antigen tests can help reduce the spread of the virus and prevent outbreaks.

Rapid antigen testing collects a nasal swab (nasopharyngeal or saliva sample for some tests), with the result displayed **within 10 to 15 minutes**. However, these tests are less accurate than a standard PCR, so have some limitations compared to the standard COVID-19 tests (PCR) used in testing clinics.

**Due to the limitations of RATS, this document provides some guidance of the potential roles of Rapid Antigen Tests** to ensure they are used in the right scenarios and the results are interpreted carefully. It can be used to discuss the pros and cons of a strategy when Rapid Antigen testing is being proposed in remote settings and discrete Aboriginal communities.

Any Queensland Health facilities will be guided by the relevant **Queensland Health CHO Direction on Rapid Antigen Tests**, Infection Control, Vaccination and Testing protocols for staff and patients. The Aboriginal and Torres Strait Islander Community Controlled Health Organisations (ATSICCHO) and Primary Health Care services should review the CHO direction when it is issued.

## Which rapid antigen tests can be used?

Test and devices that have not been approved by Therapeutic Goods Australia (TGA) cannot be used in Australia. The TGA website includes a list of all registered rapid antigen test kits that can be used by primary health care providers: <https://www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia>

Considerations in choosing a test include:

- Nasal swabs have better accuracy than saliva swabs and are less invasive than NSP swabs.
- Clinical sensitivity (higher sensitivity will reduce the number of false negatives).
- Clinical specificity (higher specificity will reduce the number of false positives).

The supply of rapid antigen tests by health services for self-testing of COVID-19 (without the direct supervision of a healthcare professional), is prohibited under the [Therapeutic Goods \(Medical Devices - Excluded Purposes\) Specification 2020](#). Rapid antigen tests must be used in accordance with the [National Pathology Accreditation Advisory Council Guidelines for Point of Care Testing](#) and COVID Safe measures should always be in place.

## Diagnostic vs screening tests

Diagnostic and screening tests have different uses.

The purpose of a diagnostic test – A COVID-19 PCR test - is to detect the presence or absence of disease in an individual suspected of having the disease.

A screening test—e.g. a Rapid Antigen Test—is used to detect disease in a group of people not necessarily suspected of having the disease. Screening tests are used primarily in people without symptoms to determine if any individual has undetected disease.

Rapid antigen testing is best suited for use as a screening test to help identify a person with COVID-19 quickly and isolate them from a group of people. This information can then be used to help reduce the spread of COVID-19 and prevent outbreaks.

## Rapid antigen tests as a screening tool – don't forget the epidemiology at the time

Antigen testing is less sensitive than PCR testing, and so there is a risk of missing cases. Repeat testing can offset the reduced sensitivity of antigen testing – the frequency of the repeat testing will depend on the context of the decision to test with RATs.

Rapid antigen tests will also produce false-positive results (an infrequent but incorrect result), especially if COVID-19 is at low levels in the group being tested. Therefore, **all positive rapid antigen tests must be confirmed by an additional confirmatory PCR test.**

In settings where COVID transmission in the community is not occurring RAT is unlikely to be of benefit. Note that a RAT is not currently documented as a formal pathology result currently.

### Appropriate settings for COVID-19 rapid antigen testing

Non-clinical settings, such as business and industry, concerned about COVID-19 in the workplace may benefit from the use of rapid antigen testing.

Health care providers and employers should note that where there is little or no community transmission of COVID-19, screening for the virus in low-risk settings (including workplaces) has limited benefit. In these situations, COVID Safe practices, should be encouraged – so COVID-19 vaccination and if symptomatic to get tested with PCR and isolate.

Rapid antigen testing can be valuable for screening purposes for occupational groups that have the potential for greater exposure to SARS-CoV-2 due to more frequent, close or extended contact with others, in settings where there is a higher risk of workplace transmission of COVID-19 infections or during periods of widespread community transmission.

**If a person has any COVID-19 symptoms or is a contact for COVID-19, they should immediately get tested using a PCR test for COVID-19 at a testing site if available**

## When should we use Rapid Antigen Tests?

There are 3 main strategies for using Rapid Antigen Tests:

- Focused Symptomatic testing
- Focused Asymptomatic testing
- Mass testing

Five scenarios are proposed in the table below. Mass testing crosses over with cluster response and is not considered in more detail.

**Table 1**

Type of testing	Role of RAT testing	Setting	Scenarios
<b>Focused Symptomatic testing</b>			
	No or poor access to PCR	Remote Setting - geography weather events	Exposed to a confirmed case or symptomatic, unable to access PCR: positive managed as case, negative do serial RAT testing
	Test delays or TAT* for PCR too long	Community COVID Prevalence High	Community transmission, high prevalence COVID setting: positive managed as case, negative do serial RAT testing
<b>Focused Asymptomatic testing</b>			
Cluster response testing	Mass screening	Potential spread in at risk setting eg RACF, remote community	Transmission already occurred from case and wider exposure expected; one off or serial: positive managed as case, negatives - review ongoing testing strategies
Test to release	Modified quarantine	School, health care, essential worker	Significant community transmission, known exposure to a confirmed case (ie Close contact) Serial test on day of attendance to confirm negative
Test to protect	Regular screening	Essential staff with front line exposure to the public	Twice weekly regular screening, Significant community transmission occurring / hot spot
Test to protect	On the spot screening	Protection of large gatherings	Screening pre-entry to large meeting/funeral/workshop, Significant community transmission occurring / hot spot

\*TAT – Turn Around Time – time period from collection of the swab to the result being issued by the Pathology Services

# How to interpret Rapid Antigen Test results

## *Epidemiology*

Whenever a decision is made to use a RAT the context in which that decision has been made must be the basis for the interpretation of the result. This will guide how to manage the person/people who are being tested.

The primary consideration are the risk of exposure for the person and community:

- Current stage of outbreak:
  - eg local clusters only – limited value, widespread
  - community transmission of COVID-19 – consider implementing RAT to minimise Turn around time issues – prioritise PCR for high risk contacts and symptomatic
- Community spread
  - households and families may utilise for modified quarantine to attend work / school if close contacts
- Recent events in communities – funerals, sporting events
  - If community transmission may use RAT for protection of mass event spread
- People coming into the community – staff or community visitors
  - If vulnerable remote community use RAT for protection screening

**Consider early consultation with the local PHU when planning implementation of RAT testing**

## *Patient Journey*

The other consideration is the timing of the test within a case's infectious period. A RAT is most likely to be positive early in the person's infectious period. The person will usually become infectious 2 to 6 days after exposure. If they develop symptoms it will typically be 2 days after they become infectious. The RAT test may remain positive for up to 10 days after becoming infectious.

So a negative RAT may be a false negative if taken too soon in their COVID infection. If a person has been exposed manage them as a positive case and repeat testing with a PCR if available or serial RATs if PCR will not be timely. A person with a negative RAT at the tail of their infection, may not be infectious depending on the timing of the test and their vaccination status.

**Again please consult with the local PHU on interpretation of results.**

## *Positive test results*

For all positive rapid antigen test results:

- confirm with a **standard COVID-19 test (PCR)** at a laboratory or testing clinic
- isolate the person awaiting further PCR testing results.

Isolating people with positive results, or symptoms, will help break chains of transmission and limit the spread of COVID-19.

Positive rapid antigen tests should be discussed with the local Public health. Only PCR test results will be formally registered as cases.



## **Negative test results**

A negative test must be interpreted in the context discussed above. Possible interpretations include

- true negative – no epi links, asymptomatic or infection cleared
- false negative – epi links and possibly conducted too early

If a false negative is suspected (eg clinically likely, significant exposure) manage the person as a possible case, and retest with a PCR if available or serial RAT

Remember that in settings where RAT is being used then significant Covid transmission will be occurring. In healthcare settings standard practices of infection control procedures, using PPE, maintaining distance, and minimising exposure should be in place. RATS may form part of your workplace surveillance – check what your local protocols require. It is not sufficiently accurate to allow interaction without protection or rely on RATS alone as up to 20% of infected people could have a negative test.

There is no requirement to formally report the result of a negative rapid antigen test. However an ATSI/CHO or primary care provider may keep a record of all tests conducted by their health staff. Trained health staff should conduct any tests within their services to ensure the most accurate result

## **Guidance for people using self-tests in the Community**

NSW Health has good guidance for the community

[Rapid antigen self-tests for community \(COVID-19\) | NSW Government](#)

Therapeutic Goods Administration guidance for safe implementation

The TGA has published guidance including a checklist to assist businesses understand the key considerations for the safe implementation of COVID-19 rapid antigen point-of-care testing in their workplace.

For more information on the guidance please contact [COVIDtests@tga.gov.au](mailto:COVIDtests@tga.gov.au) or call 1800 141 144

- [COVID-19 Rapid Antigen Tests - Guidance and checklist for businesses | Therapeutic Goods Administration \(TGA\)](#)
- [COVID-19 rapid antigen self-tests that are approved in Australia | Therapeutic Goods Administration \(TGA\)](#)

## Appendix 1

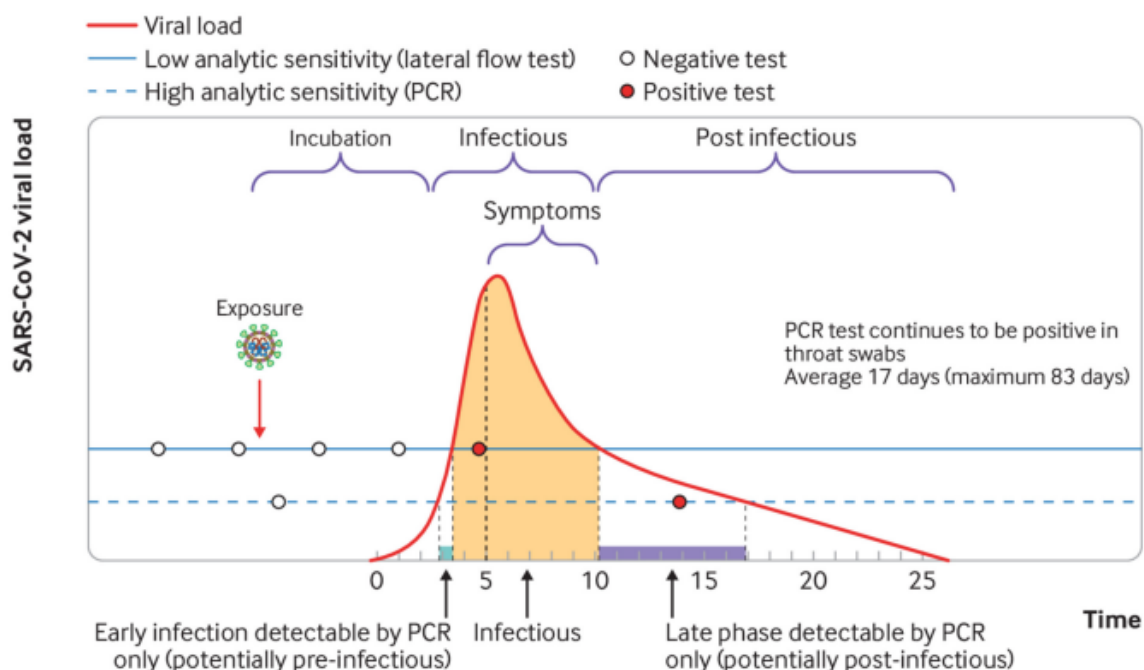
### How to undertake Rapid Antigen Tests

Most manufacturers of the tests will have videos on their websites. Queensland Health has some videos on using PPE and protection while testing and two RATS – the Innoscreen Rapid Antigen Test and Panbio COVID-19 Ag Nasal Swab tests

Queensland Health how to Rapid Antigen Test videos: <https://qheps.health.qld.gov.au/pathology-queensland/rapid-antigen-testing-videos/> [nocache](#)

## Appendix 2

The diagram below shows a person's journey through a coronavirus infection from the point of exposure. The orange shaded portion shows the time period in which a RAT is most likely to be positive, with a standard PCR test possibly becoming positive 1-2 days earlier in the infectious period and persisting later even though the patient may no longer be contagious



RATs; High frequency testing with low analytic sensitivity versus low frequency testing with high analytic sensitivity. A person's infection trajectory (blue line) is shown in the context of two surveillance regimens (circles) with different analytic sensitivity. Higher frequency testing is more likely to test in the infectious window. Therefore, although both testing regimens detect the infection (orange circles), the high frequency lateral flow test (or RAT) is more likely to detect it during the transmission window (shading), despite its lower analytic sensitivity. The figure is not an accurate representation of exactly when a positive test is likely to signify that a case is infectious. Adapted with permission from Mina et al16 with data from Cevik et al1 2

## Appendix 3

### Notes on the Strategies

#### Focussed Symptomatic testing

If there is poor or interrupted access to PCR testing or TAT have gone beyond a 24-48 hour TAT for PCR due to remoteness or weather events a decision may be made to use RATS. This will assist in diagnosis.

*Advantages:* RATS enable

- rapid identification and isolation of a probable case
- early contact tracing
- early treatment for them

If no testing other than RAT is available then serial RATs over a week as a proxy for PCR may be considered for example every 2<sup>nd</sup> or 3<sup>rd</sup> day.

#### Focussed Asymptomatic Testing

##### 1) Cluster response testing

In a discrete population where a mass spreading event may have occurred and the scope of the outbreak needs to be quickly assessed.

A mass screening can indicate the prevalence of acute cases in a community or setting like an RACF quickly.

*Advantages:* mass screening can allow for rapid mobilisation of resources in sufficient scale to assist with the response if large numbers of cases are found. Rapid mass screening can aid in reassurance of a community at the start of a potential outbreak

*Risks:* false negatives may give an impression of 'negative for COVID' – for exposed close contacts or households quarantine would still be required. Serial testing may catch people converting to positives due to initial testing being too early in the disease process.

##### 2) Test to release or protect - modified quarantine or regular screening

In some settings where large numbers of people gather or for close contacts who must work and can not quarantine, RATS may enable early detection of COVID. Staff in these settings should be vaccinated.

Settings

- schools where repeated quarantining is detrimental
- health care facilities, aged care facilities or correction centres where staff are required to work despite close contact exposure.

Discuss testing schedules with the local PHU:

- daily, 2<sup>nd</sup> or 3<sup>rd</sup> day scheduling with testing (for 7 days for close contacts)
- a weekly PCR may be recommended

Self-testing at home in quarantine prior to going to work or school maybe an option, or a dedicated stand set up a facility to provide testing.

*Advantages:* reduces impact of furloughing on staff and students



*Risks:* home testing may have some reduced sensitivity. Symptomatic close contacts should have a PCR wherever possible.

Disadvantage: risk of false negative leading to unsafe behaviour (risk reduced by repeat testing but should still wear PPE etc to reduce risk), in low prevalence setting risk of false positive undermining confidence in the test

### **3) On the spot screening in settings of community spread to protect vulnerable people**

Some settings will want to test people prior to entry, when people have visited a hot spot or there is local transmission of COVID in their community

- to minimise risk of mass spread event such as funerals or sports events
- to protect vulnerable population eg aged care facility visitors, hospital admissions

*Advantages:* added layer of safety in performing a screening test in an otherwise untested cohort so 100% “false negatives” because no testing at all.

*Risks:* if done in a setting of low prevalence false positives undermine confidence in test. Additional resourcing requirement needs justification of risk being sufficiently high ie community transmission occurring. Maintain protections after a negative test.

## **References**

Put to the test: use of rapid testing technologies for covid-19. A Crozier, S Rajan, I Buchan, M McKee. BMJ 2021;372: n208 <http://dx.doi.org/10.1136/bmj.n208>

[NSW Health: Rapid antigen self-tests for community \(COVID-19\) Website: \*\*Rapid antigen self-tests for community \(COVID-19\) | NSW Government\*\*](#)

[Rapid antigen self-tests | Coronavirus Victoria](#)

[Guidance for the provision of rapid antigen testing for COVID-19 screening in non-clinical settings | health.vic.gov.au](#)

NSW Health Framework for the Provision of Rapid Antigen Screening for COVID-19 in Clinical and Non-Clinical Settings [209659 RAS Framework and Standard Operating Procedure Nov15 v1.pdf \(nsw.gov.au\)](#)

COVID- 19 Rapid Antigen Point of Care Testing. Guidance for implementation and Checklist for businesses. TGA September 2021 [COVID -19 Rapid Antigen Point of Care Testing \(tga.gov.au\)](#)