Australian Government
National Health and Medical Research Council

NHMRC

National COVID-19 Health and Research Advisory Committee*

Date of advice: 1 October 2021

Advice 26: Implementation of Rapid Antigen Testing in various settings

Focus

To provide evidence-based advice on the suitability of point-of-care (POC) rapid antigen tests (RAT) for managing community transmission of SARS-CoV-2 in various occupational, educational and healthcare settings and discuss how different levels of community transmission may influence decision making.

This advice builds on the advice provided in Part 1 which summarised the evidence on the utility of POC RAT in managing ongoing community transmission of SARS-CoV-2.

Note

This report is point in time and may need further updating as more evidence is available.

This report was developed with the assistance of a working group of the National COVID-19 Health and Research Advisory Committee (NCHRAC), chaired by Professor Bart Currie, with Professor Michael Good, Drs Katie Allen and Mike Freelander and Mr Daniel Zhou.

Overarching key points:

- Due to the relationship between viral load and infectiousness, RAT are thought to detect a high proportion of infectious cases, while being less likely than PCR to detect both early infection and post-infectious shedders.
- The shortened time for receiving results from RAT, compared to PCR, can enable early identification and isolation of infected individuals and timely contact tracing.
- Algorithms for use of RAT in different occupational, educational and healthcare settings need careful consideration, taking into account current rates of COVID-19 infection, vaccination rates in the target population, geographical location, access to health care and follow up, community support and access to safe quarantine for those with positive results.
- The implications of a false negative RAT test also need consideration for each developed algorithm covering a specific setting of use.
- The following guidance is based on the international literature and pilot programs conducted in Australia trialling RAT:

* NHMRC is providing secretariat and project support for the Committee, which was established to provide advice to the Commonwealth Chief Medical Officer on Australia's health response to the COVID-19 pandemic. The Committee is not established under the NHMRC Act and does not advise the NHMRC CEO.

NCHRAC Conclusion 1 – Symptomatic testing: RAT may be used for provisional diagnosis of SARS-CoV-2 infection in settings where speed is important for patient management and/or disease control, pending confirmation with a molecular test.

NCHRAC Conclusion 2 – Protective screening of high-risk populations: Serial or regular screening using RAT can assist in detecting asymptomatic individuals in high-risk populations where an outbreak of SARS-CoV-2 will have a high impact.

NCHRAC Conclusion 3 – Testing to enable activities: There is evidence that RAT can be an effective screening tool, when conducted regularly, to identify infectious cases of COVID-19 in workplaces and schools.

NCHRAC Conclusion 4 – Travel and quarantine: RAT can been used to screen passengers, particularly those travelling from a place with a higher disease prevalence than the final destination.

NCHRAC Conclusion 5 – Community surveillance including at-home testing: Offering RAT to target populations during outbreaks can assist with controlling transmission.

Summary of evidence

RAT offers an efficient alternative to the 'gold standard' PCR test to detect individuals infected with SARS-CoV-2 in specific circumstances. The international literature has demonstrated that RAT can be applied as a screening tool in various settings to complement existing public health measures to break the chain of transmission.

NCHRAC has examined the international literature and the key elements of various pilot studies in Australia to identify the risks and benefits of the application of RAT in the following contexts: symptomatic testing, protective screening of high-risk populations, testing to enable activities, testing for travel and quarantine, and cluster response testing (illustrated in Figure 1).

A list of current pilot projects involving antigen testing in various settings has been compiled and is available in **Appendix 1**.

Symptomatic testing

NCHRAC Conclusion 1 – Symptomatic testing: RAT may be used for provisional diagnosis of SARS-CoV-2 infection in settings where speed is important for patient management and/or disease control, pending confirmation with a molecular test.

Key points and advice:

- RAT may be appropriate for providing a provisional diagnosis of SARS-CoV-2 infection and appropriate infection prevention and control measures implemented.

- False negative results are possible in symptomatic patients. In analysing RAT negative results, consideration should be given to the clinical presentation of the patient as well as the epidemiological history of potential exposure.
- Clinicians and public health officials should weigh up the following factors when using antigen results to make clinical decisions:
    - The capacity and ability for pathology to provide timely RT-PCR results.
    - Availability of POC molecular SARS-CoV-2 test facilities.
    - The ability/practicality for the clinic, health service etc. to isolate people with symptoms consistent with COVID-19 who are RAT negative until molecular results are available.

Settings include:

- Requirement for urgent provisional diagnosis (e.g. presentation to emergency, pre-operative screening).
- Isolated and remote settings where laboratory access is limited and/or where capacity of rapid molecular tests, such as POC PCR Xpert SARS-CoV-2 test, is overwhelmed by active COVID-19 transmission.

In some circumstances, screening symptomatic populations with RAT may be appropriate. A technical report on antigen testing by the European Centre for Disease Prevention and Control recommends their use for people with symptoms in the following scenarios: high disease prevalence settings, closed settings such as prisons where a confirmed case exists, social/healthcare triage and situations where RT-PCR is not available.[1]

The use of RAT for symptomatic testing has shown to be beneficial in limiting community transmission in remote, isolated and regional communities in Alaska where access to timely laboratory based PCR testing is limited.[2,3] The use of RAT in this setting enabled the prompt identification and isolation of infected individuals and timely contact tracing.

Testing of symptomatic patients enables the rapid provisional identification of infectious individuals in frontline and semi-closed environments so care can be provided with the appropriate measures in place to limit transmission to others and accelerate the management of the infected patient.[4-8] RAT has shown higher sensitivity in people who have COVID-19 consistent symptoms. A preliminary publication of a trial involving 3410 emergency department patients (991 patients with COVID-19-like symptoms and 2419 asymptomatic patients) reported a significant difference in the sensitivity for symptomatic patients 89.9% (95% CI 85.4%–94.4%) to asymptomatic patients 50.0% (95% CI 36.0%–63.0%).

RAT has the benefit that it can quickly identify infectious patients who present for care with COVID-19 like symptoms. However, in clinical settings such as emergency rooms, a false negative RAT result could have serious implications if relaxation of isolation protocols resulted in exposure of patients and/or health/social care staff. A total of 22 false negative and one false positive result was observed in a trial of rapid antigen testing (Roche SD Biosensor SARS-CoV-2 rapid antigen test) involving 473 patients (symptomatic or close contacts) presenting to an emergency department. Patients with a false negative RAT with

symptom onset at least one week earlier were found to have a low SARS-CoV-2 RNA concentration and therefore were considered unlikely to be infectious. However false negative test results did occur in some patients with high viral concentrations, who are likely infectious.[9] Sampling technique or handling errors may have contributed to this outcome.

Based on these results, a RAT cannot be used to confidently exclude SARS-CoV-2 infection in symptomatic patients. Those who test negative should stay isolated until the molecular test result becomes available. Fortunately, if symptom onset occurs more than 7 days prior to testing there is a low chance the patient would still be infectious.[8,9]

Even in settings where there is a delay in receiving pathology results, confirmation of diagnosis using molecular testing still remains essential.[5]

NCHRAC Conclusion 2 – Protective screening of high-risk populations: Serial or regular screening using RAT can assist in detecting asymptomatic individuals in high-risk populations where an outbreak of SARS-CoV-2 will have a high impact.

Key points and advice:

- RAT can be considered as an alternative to daily/once per shift saliva PCR screening.
- Daily (or before commencement of shift) RAT can be considered as an alternative to isolation for fully vaccinated health care workers who have been identified as close contacts (once a negative initial PCR result is obtained).
- False negative results are possible when using RAT to screen high-risk populations; however this risk needs to be considered in light of the fact that negative RAT results do not abate the primary role of the use of non-pharmaceutical interventions such as physical distancing and use of PPE.
- Serial testing enhances the efficacy of RAT (see Background).

Settings include:

- Screening for high-risk populations (e.g. health care workers and quarantine workers).
- Closed and semi-closed residential settings (e.g. prisons, aged care).
- Isolated and remote communities where there is community transmission.

Strategies for use of RAT vary internationally; however, many countries have focused efforts on asymptomatic screening in closed and semi-closed settings such as hospitals, care homes, prisons and hospices.[10] In these settings there is an increased risk of COVID-19 transmission due to close proximity and difficulties maintaining physical distancing and potentially a large number of people who are vulnerable to severe disease from COVID-19 (e.g. due to age or medical conditions).[11]

With the current high prevalence of COVID-19 in NSW, residential aged care settings have been the focus of RAT pilots. In these pilots, aged care workers are subject to testing each shift in an attempt to prevent an outbreak in aged care facilities in Greater Sydney. The Federal Government has provided RAT to aged care providers in high-risk LGAs in NSW. Further details are included in **Appendix 1**.

As of late September 2021, NSW Health is using saliva PCR for healthcare workers and in all their NSW Health quarantine and surveillance and testing program.[12,13] A saliva sample is estimated to be roughly 85% as accurate as a nose and throat swab. Saliva samples are favoured over nasopharyngeal samples for surveillance due to the ease of collection. Serial testing (daily or once per shift) increases the sensitivity.[14] The use of saliva as a respiratory specimen for SARS-CoV-2 PCR testing reduces the need for personal protective equipment, supervision of sampling and the collection method is less invasive and socially acceptable.[15]

Screening of asymptomatic workers supports other infection control strategies and can pick up infections early.[16-18] RAT screening for healthcare workers has been implemented successfully in a number of overseas countries and offers a faster and less expensive alternative to daily saliva PCR for Australia. For example, all unvaccinated frontline healthcare workers in Singapore will be required to complete a RAT twice per week from 1 October 2021.[16]

In the United Kingdom, all National Health Service (NHS) staff and vaccination site volunteers have been able to order RAT kits directly from the government since July 2021.[17] All NHS staff have been instructed to test twice a week depending on work patterns (ideally in the morning before a shift). Reporting of all results (positive, negative and void) is a statutory duty and must be done via a local reporting procedure or via a government reporting website.[18] Also, vaccinated health care workers that have been identified as a close contact of a COVID-19 case who as asymptomatic and have a negative PCR test result are required to undergo daily RAT for a period of 10 days as an alternative to isolation.[19] In this scenario, the use of RAT allows for fully vaccinated staff who are close contacts to re-commence work immediately following their negative PCR result.

Following outbreaks in the NSW custodial settings, the Justice Health and Forensic Mental Health Network (the Network) spokesperson announced on 31 August 2021 that RAT is being rolled out across NSW prisons, youth justice centres and police cells to provide a fast and effective way of identifying and isolating potential cases.[20]

In April 2020, the Federal Government announced a remote POC testing program at 83 sites servicing remote Indigenous communities. The program, developed by the Kirby Institute and the Flinders University International Centre, utilises the POC PCR test, Xpert SARS-CoV-2 test which can provide a result in 45 minutes.[21] The use of POC PCR in these settings offers technology that is portable and has high sensitivity. However a number of barriers have presented in that there are limitations in throughput, limited cartridge supply, instrument maintenance and operator training requirements. RAT could be used in this setting to compliment rapid molecular tests to overcome some of these issues.[22,23]

Interestingly, in the Northern Territory, the surveillance testing strategy for quarantine staff at the Howard Springs facility recently changed from RAT to weekly nasopharyngeal PCR with daily salivary PCR. A representative of the Northern Territory, Deputy Chief Health Officer cited concerns over the sensitivity and false negatives as the reason for the change. It should be noted that PCR tests that use saliva samples are less sensitive than nasopharyngeal swabs and have a sensitivity comparable to RAT.[12]

NCHRAC Conclusion 3 – Testing to enable activities: There is evidence that RAT can be an effective screening tool, when conducted regularly, to identify infectious cases of COVID-19 in workplaces and schools.

Key points and advice:

- Clear communication about the interpretation of negative results is important to avoid engendering a false sense of assurance or complacency.
- RAT screening 2-3 times per week is commonly reported in the literature. The optimal frequency of testing depends on a number of factors such as:
    - the level of community transmission
    - the level of close or prolonged contact
    - the level of vaccination in the community.
- States and territories should develop and share Standard Operating Procedures (SOPs) for screening requirements; for example in travellers crossing jurisdictional borders by road such as long-haul truck drivers.
- In regard to concerns of false negatives, results need to be interpreted in the context of the epidemiology of exposure:
    - The viral load for RAT false negatives is suggested to be of a range that is not considered infectious at that point in time.
    - Serial screening enhances the sensitivity of testing and reduces the incidence of false negatives (see Background for more details).
- The sensitivity of antigen screening of school-aged children may be less than that of the adult population.
- Daily RAT testing of close contacts of COVID-19 cases following a negative PCR may enable workers and students to remain at work or school instead of isolating for 14 days.
- Disincentives to participate in screening, such as financial or other negative consequences of a positive result, should be addressed in workplace screening programs.

Settings for screening include:

- Workplaces with close and/or prolonged contact (e.g. mining, freight/delivery drivers crossing jurisdictional borders, food processing, construction).
- Workplaces with high level of contact with the public (e.g. hospitality, law enforcement, border control).
- General workforce (e.g. offices, small business, retail).
- Secondary schools, educational facilities (staff and students).

- General workforce screening

The **NSW Government Framework for the Provision of Rapid Antigen Screening for COVID-19 in Clinical and Non-Clinical Settings** states rapid antigen screening may be appropriate when tests are performed at frequent intervals (2-3 time per week) as a screening tool for

COVID-19 in asymptomatic employees in a range of industries. The benefits of rapid antigen screening are greater in settings with high disease prevalence. At low levels of disease prevalence, a high proportion of positive results will be false positives, which impacts the public health benefit of RAT.[24]

As Australia's vaccination rate increases and we move to living with a degree of COVID-19 in the community, the use of frequent RAT screening can reduce the operational and business-related impacts of public health measures/restrictions and staff absences. RAT is particularly useful as a screening tool in occupational settings where there is frequent close or extended contact; e.g. construction workers, border control, law enforcement officers, air and maritime staff, child care and teaching).

Similar to Australia, companies in Canada (Bank of Nova Scotia, Suncor and Air Canada)[25] have piloted RAT projects with the aim of returning people to workplaces safely. Ontario Canada rolled out RAT as a screening tool and layer of security for workplaces in addition to routine workplace public health measures. In the pilot phase of the project, from November 2020 to 31 March 2021, 160 employers representing four priority settings: health care, congregate living, essential workplaces and industry settings were provided with 2-3 kits per employee per week.[26] In this program, employees who were symptomatic or RAT positive were directed to testing centres. In addition, the testing was not used when there was either a confirmed or suspected outbreak in a workplace setting or for symptomatic individuals or close contacts of positive cases (who were directed to testing centres). The pilot data from asymptomatic people showed a positivity rate of approximately 0.25% with testing supervised by a trained individual. This outcome demonstrated the ability of the tests to identify asymptomatic cases that would have likely gone undetected.

Transport and freight workers represent another high-risk population due to the nature of their work and regular travel to/from/through areas of community transmission. While state and territory borders are subject to closures and restrictions, for transport and freight workers to cross road borders, there are requirements such as obtaining permits and confirmation of recent negative PCR tests.[27-29]

RAT offers logistical advantages to supporting screening of freight and transport workers crossing jurisdictional borders. In South Australia (SA), as of 13 September 2021, freight workers are allowed entry if they have a negative COVID-19 test that occurred 72 hours prior to arrival. Otherwise they will be required to undertake a POC RAT and/or a COVID-19 test 12 hours prior to entry. As of 27 September, SA implemented a border RAT program for certain freight and transport workers at two border crossings (one with NSW, one with Victoria). In Western Australia, since early-mid September2021, freight workers arriving from Victoria or NSW must produce evidence of a negative COVID-19 test taken within the last 72 hours or if they cannot produce results, they must undergo a RAT at the SA or NT border crossing.[30]

Operationalising RAT screening at road borders has significant challenges and it is important for states and territories to share resources and experiences. SOPs for border RAT screening need consider various complications, including:

- Drivers with English as a second language
- How to travel to location in a COVID safe manner
- Vehicles with more than one driver or convoys
- Entry into regional towns with large freight vehicles
- Considerations for livestock and hazardous material loads
- Route to travel to confirmatory testing location
- Appropriate parking at truck stop and decoupling of load if required
- Liaison with road/transport authority counterparts for assistance[31]

Screening for primary and secondary schools

The NSW Government has published guidance for the introduction of RAT in school settings.[24] A factsheet for schools, students and parents states that screening for students will take place at least twice per week for the purpose of quickly identifying and isolating students who may have COVID-19. Recruitment of schools to participate in an initial trial is underway, but all schools are encouraged to implement RAT for their students.[32]

Two recent studies investigating accuracy of antigen testing in children have highlighted limitations in asymptomatic children.[33,34] A clinical study on RAT including 885 paediatric patients found sensitivity in asymptomatic children to be poor with higher (but still suboptimal) sensitivity in children with symptoms. Sensitivity of RAT in children with high viral loads exceeded 80% indicating higher identification of children who are contagious.

An evaluation of RAT sensitivity for children (aged 5-18) at a community testing site in Wisconsin, USA found that, compared to RT-PCR, sensitivity was 73.0% (27/37) for children and 80.8% (240/297) for adults. Importantly, in this trial all culture-positive specimens from children had a positive antigen test, indicating that antigen testing identified children with live SARS-CoV-2 virus.[35]

A large study by the University of Oxford in the United Kingdom involving over 200,000 students and 20,000 staff that compared the isolation of close contacts of COVID-19 cases for 10 days with regular PCR testing compared with close contacts of positive cases who participated in RAT on arrival at school. The study found daily testing of students and staff who were close contacts was just as effective as isolation in controlling spread of infection. Of those contacts required to isolate, 98% did not develop COVID-19.[36] This study suggests that daily testing was able to identify most of the small proportion of children who developed COVID-19 while allowing students and staff to remain in school.

Despite the suboptimal sensitivity of RAT in children, testing in schools may provide a public health benefit and Australian trials are underway.

Pre-event testing

There is preliminary evidence that when combined with other interventions such as facemasks and air ventilation, same day RAT screening may increase the safety of mass-gathering indoor events.[37] In a randomised controlled open-label trial, participants were randomised to either enter the music event (experimental group) or continue with normal life (control group) immediately following a RAT. In this study, none of the participants who

attended the concert had RT-PCR-confirmed SARS-CoV-2 infection at 8 days after the event. The results suggest that RAT screening might allow some recommencement of indoor events.[37]

In Singapore, RAT forms part of their Pre-Event Testing (PET) program. In this program, the requirement for screening only applies to people who are not covered by an approved vaccine. Children 12 and under and those who have recently recovered from COVID-19 are also exempt. To attend events that are under the PET program, a person must have evidence of a negative COVID-19 Test result 24 hours (RT-PCR or RAT) before the event.[38]

Testing for travel and quarantine

NCHRAC Conclusion 4 – Travel and quarantine: RAT can been used to screen passengers, particularly those travelling from a place with a higher disease prevalence than the final destination.

Key points and advice:

- RAT screening on the day or departure or date of arrival, for long haul flights, assists in reducing the risk of transmission during travel.
- RAT can also be used to monitor individuals in home or managed quarantine settings after arrival.

Settings include:

- Pre-departure or on arrival screening for air or maritime travel.
- Home or managed quarantine settings.

Travel screening

As vaccination rates around the world increase and international borders start to reopen, many countries have implemented 'test to travel' strategies. These strategies aim to reduce the risk of SARS-CoV-2 transmission during travel as well as the importation of infection, particularly when travelling from a high to low incidence setting.

Pre-travel testing 2-3 days prior reduced the number of actively infectious travellers on the day of travel with greater success compared to the use of longer lead times of 5–7 days. Routine screening of asymptomatic individuals for SARS-CoV-2 with RAT on the day of travel or PCR testing within 3 days before appeared to have similar benefits for reducing the number of infectious travellers (when assuming performance characteristics for the RAT have 90% of the sensitivity of PCR during the active infection period).[39] Additional benefit is seen with abbreviated quarantine and post-travel testing 5 days after arrival. Kiang et al noted that both PCR and RAT pre- and post-travel screening have their limitations, however, they do provide a useful tool alongside physical distancing, universal wearing of facemasks, and other infection control measures during travel.

All travellers entering the UK are required to perform a pre-flight COVID-19 test within 3 days prior to departure. The test is required to meet the performance standards of ≥97% specificity, ≥80% sensitivity at viral loads above 100,000 copies/ml. This includes tests such as a PCR test, LAMP test and RAT. RAT are recommended for people previously infected with

COVID-19 due to sensitivity of PCR tests.[40] The need to quarantine and the length of time is dependent on the prevalence of COVID-19 in the country departed and the individual's vaccination status.

Japan has implemented a two-step screening process requiring nucleic acid amplification tests (NAAT) 3 days before departure and on arrival at the airport.[40] On arrival self-collected saliva is screened using chemiluminescent enzyme immunoassay (CLEIA) for antigen and confirmatory NAAT is required for intermediate range antigen concentrations. This reduces the burden on laboratory based analysis and provides rapid results.[41]

- Quarantine after international travel or close contact of a positive case

Current WHO recommendations for quarantine are based on the maximum incubation time observed in studies done during the beginning of the pandemic.[42] Fourteen day quarantine of an individual that has been a close contact of a positive case or has arrived from a place with a higher disease prevalence to the final destination is a strategy to reduce the spread of infection. This can have a negative economic, operational impact on businesses and mental health impact on employees that are required to frequently travel (e.g. mining, air and maritime workers) or are at a higher risk of exposure to infected individuals (i.e. healthcare workers).

The UK has developed a traffic light system that guides an individual's quarantine requirements on international arrival that is dependent on the disease prevalence of the country departed. Arrivals from red list countries (i.e. higher disease prevalence) are required to go into managed quarantine for 10 days and undergo COVID-19 testing on day 2 and day 8. Individuals vaccinated with a recognised vaccine from medium risk or 'amber' countries are not required to quarantine but are required to take a COVID-19 test on day 2. Unvaccinated individuals are required to self-quarantine at home for 10 days and undergo testing on day 2 and 8 unless they opt to 'test to release'. This entails an additional test on day 5 and if negative they can be released from quarantine early. People arriving from 'green' or low risk countries are not required to quarantine and only perform a COVID-19 test on day 2.

In Singapore, people who are required to isolate may do so at home, a quarantine facility or hospital. Returning travellers requesting home quarantine has seen over 20,000 applications, but as of 10 August, only 4,159 had been approved for home quarantine. Factors influencing decisions include the infection risk in the country of departure, the number of people living in the address nominated as the home quarantine, the number of rooms and rooms with adjoining bathrooms.[43] Those approved to serve their quarantine period at home are subject to a number of testing requirements. In addition to entry and exit RT-PCR testing, people in quarantine must complete daily self-administered RAT and must receive a negative RAT result before attending a RT-PCR testing site to exit quarantine.[44]

In Japan, mandatory quarantine for 14 days is required at home or in managed accommodation, depending on the last point of departure.[45] A revised quarantine period for

ten days is to be announced soon for people who have received two doses of a COVID-19 vaccine approved in Japan — Pfizer, Moderna and AstraZeneca.[46]

Community surveillance

NCHRAC Conclusion 5 – Community surveillance including at-home testing: Offering RAT to target populations during outbreaks can assist with controlling transmission.

Key points and advice:

- Targeted community screening such as door-to-door, home delivery (when self-testing is approved) or pop-up testing sites may be an effective way to identify COVID-19 infections.
- In the lead up to the expected approval of RAT at-home tests, instructional resources for the correct administration of the various self-sampling methods should be developed to maximise test performance.
- Documentation of results, data management and sharing of data, RAT testing algorithms and SOPs across jurisdictions all need attention and support to maximise the public health benefit of use of RATs in Australia.

Offering RAT widely in areas of high prevalence has the potential to find cases early and reduce overall transmission without putting strain on the RT-PCR testing capacity.[10] Community surveillance in outbreak areas can be achieved with both supervised and self-administered antigen testing.

- Community surveillance

Community screening with rapid antigen tests, alongside other public health measures, may offer an opportunity to recommence social and economic activities. Screening the community can be achieved with various strategies depending on the level of disease and type of community. Strategies include, once-off mass screening, serial testing, targeted distribution of tests and 'pop-up' sites. Some strategies require approval of home testing, which is currently unavailable in Australia but expected to be approved in the coming months as Australia enters the next phase of its pandemic response.[47]

Community surveillance with RAT has had some success internationally. A mass community testing intervention in Slovakia that ran over the course of three weeks, screened 65% of the population with RAT. Screening took place during a period of high disease prevalence (up to 3.9%) and identified more than 50,000 people without COVID-19 symptoms who were likely to be contagious with SARS-CoV-2.[48] In the week following this study, a 50% decline in infection prevalence was observed. Although this outcome cannot be directly attributed to the RAT screening, the outcome suggests that a mass screening program where positive cases are isolated could be as, or more, effective than mass lockdowns as a public health measure.[49] However the resourcing requirements are high.

In the United Kingdom a large number of COVID-19 tests are available to individuals, which vary in price and may be self-administered or supervised. RAT are recommended for

asymptomatic individuals. PCR tests are only recommended for people displaying symptoms, people arriving from specific amber list countries or close contacts of COVID-19 cases.[50]

A mass screening program in early 2021 tested 283,338 (57%) of the residents of Liverpool between 6 November 2020 and 30 April 2021 using Innova SARS-CoV-2 RAT. Of these participants, 152,609 took a PCR test either because they had symptoms or to confirm a positive asymptomatic RAT result. The rate of positive results for individuals tested by RAT was 2.1%. For symptomatic individuals (who were tested with RT-PCR), the positivity rate was higher as expected, at 14.8% (reflecting that they are or have been infected with COVID-19). RAT identified most COVID-19 cases without classical symptoms but with high viral load (i.e. those likely to be the most infectious) and the screening pilot led to an estimated 21% reduction in cases.[51] Overall, the RAT screening program was able to extend the reach of other health protection measures.

Internationally, testing events in localities of high incidence and outbreaks have be trialled. For example, a "pop-up" model has been used in Nova Scotia, were RAT was offered on the spot in locations such as community centres, food service establishments and entertainment facilities.[3] The pop-up model was successful and had several positive impacts including engagement with communities, education and increased awareness, reinforcement of other public health measures and destigmatisation of testing.[3]

In Australia, the Federal Government has made RAT kits available from the National Medical Stockpile to residential aged care, home care, short-term restorative care and services delivered through the Commonwealth Home Support Programme operating in high-risk local government areas (LGA) in Greater Sydney and other areas of NSW.[52]

- At-home testing

Validation of the sensitivity of RATs approved for self-administration (versus completed or supervised by a health professional) is important to understand the real world sensitivity of RAT performed at home.

Procedural errors when self-sampling (nasopharyngeal) include:

- incorrect angle insertion of swab
- incorrect depth of insertion of the swab
- insufficient duration/rotation/rubbing when swabbing
- unilateral sampling.[53]

Test performance can be hampered by:

- nervousness
- fever or other symptoms
- poor concentration
- aversion to self-sampling
- language barriers
- limited fine motor skills.[53]

At-home testing has been validated as a reliable alternative to professional nasopharyngeal sampling, with a single centre study of 289 participants finding positive percent agreement of 90.6% (95% CI 75.8–96.8%) and negative percent agreement of 99.2% (95% CI 97.2–99.8%). Participants in this study collected samples with real time verbal instruction.[54] Similar results were observed in another study of 144 participants which found positive percent agreement between self-testing and professional testing on RAT was 91.4% (CI 77.6–97.0); the negative percent agreement was 99.1% (CI 95.0–100). In this study participants were given illustrated and written instructions.[53]

A longitudinal comparison of high frequency RAT compared directly with RT-PCR specimens found that twice weekly at-home RAT detected infections with 96.3% sensitivity (257 individuals, 2951 paired samples) on days 0-3 of symptoms.[55]

One evaluation of the Abbott BinaxNOW COVID-19 Ag Card observed a trend towards lower sensitivity when the RAT was performed by an individual patient/caregiver versus a trained healthcare worker (57% vs. 74%, p=0.10).[56] Another study with the STANDARD Q COVID-19 Ag Test a sensitivity of 82.5% (95% CI 68.1–91.3) and 85.0% (95% CI 70.9–92.9) for self and professional sampling respectively when comparted to RT-PCR.[53]

These results suggest that, with the required resources and instructions, laypeople can reliably perform a SARS-CoV-2 RAT. At-home testing has been employed internationally in countries such as the United Kingdom and Singapore. In the United Kingdom, regular testing for COVID -19 using RAT is encouraged by the government. Test kits are available from a pharmacy or home delivery.[57] The Singapore Ministry of Health is progressively distributing RAT self-test kits to all households from 28 August to 27 September 2021 as a convenient and quick measure to give peace of mind to any individual worried about possible contact with a positive case.[58]

The TGA is progressing work that would allow the provision of at-home antigen COVID-19 testing in the future. On 27 September, the TGA published a checklist for information that sponsors will be asked to provide in response to their registration of interest to supply a COVID-19 rapid antigen self-test.[59] At-home testing will enable mass screening in samples of the population and, alongside contact tracing, can help focus the containment effort in affected communities and assist with relaxing lockdown restrictions.

Background

Sensitivity and specificity of TGA approved RATs

As at 3 September 2021, the TGA have approved 24 POC RATs that either do not require the use of laboratory equipment or require the use of small fluorescent readers for immunofluorescence-based lateral flow technology assays.[60]

Data management and reporting of results

A key element of all testing permitted in Australia is reporting/documentation. The flow of information on hardware, or results via mobile apps etc., can support analysis, recording, reporting together with the dissemination of results. However, for this to be available the infrastructure involved needs to be fit for purpose. Documentation of results, data management and sharing of data, RAT testing algorithms and SOPs across jurisdictions all need attention and support to maximise the public health benefit of use of RATs in Australia.

The total number of tests undertaken is not currently recorded or reported to a central location. In the NSW Framework it is proposed that data collection from a number of industry and school sites will occur. The framework states they will collect and report basic data in line with the evaluation plan.

- Daily online data entry for that day's test data from each site (SurveyMonkey)
- One-off survey to be completed by manager at each site
- Followed up by short phone interviews also with site managers

Impact of serial testing methodology on the sensitivity and specificity of RATs

There is growing interest in the potential use of serial RATs as part of COVID-19 diagnosis strategies in Australia.[61] A longitudinal assessment by Smith *et. al.* investigated the impact of frequent testing and found that serial testing multiple times per week increases the sensitivity of antigen tests. The frequency of testing was found to be of high importance for RAT as sensitivity dropped from greater than 98% for testing at least every 3 days to 79.7% (95% CI, 74.7%–84.1%) for weekly testing. This reduction in sensitivity was not observed for the RT-PCR tests.[14]

The sensitivity changes over the course of SARS-CoV-2 infection must be considered when evaluating the added value of serial testing for RATs. A longitudinal assessment of the Diagnostic Test Performance of both RT-PCR and a rapid antigen test (Quidel SARS Sofia – approved by the TGA) over the course of acute SARS-CoV-2 infections found that in the days prior to the infectious period, the sensitivity of RATs are substantially lower than that of RT-PCR, which limits their ability to identify individuals before they can transmit to others. During the infectious period, RAT peaks in sensitivity which subsequently declines quickly during the recovery stage of infection.[14]

Those in opposition to the use of RAT for COVID-19 screening and diagnosis have highlighted the risk of false negatives because of lower sensitivity.[62] The inherent limitations in analytical sensitivity and specificity of antigen tests in comparison to the gold standard RT-PCR should be weighed against the potential for expanded testing due to reduced costs and the ability to obtain real time results at the point of care. RAT as a screening complement to highly sensitive diagnostic tests may capture and diagnose more of the infected population despite lower levels of sensitivity. In mid-2020 the Centers for Disease Control and Prevention (CDC) estimated that only one in ten COVID-19 cases were being diagnosed in the United States which reduced the effective sensitivity of their testing regime to 10%.[63,64]

Due to the ability to reach more people, RAT may be a viable option to mitigate an ongoing epidemic. This hypothesis was tested with a simulation where prevalence of infection reached 4%. The model by Larremore *et. al* found that testing 75% of the population every three days would reduce incidence by 88% and enable control in 6 weeks. Public health benefits (a reduced peak and shorter outbreak) were also observed with weekly testing of 50% of the population.[65] Frequent serial RT-PCR is the optimal testing option; however, limited laboratory resources mean that this strategy is often not feasible on a large scale. Antigen testing with a frequency of twice weekly offers a good alternative.[14]

Impact of variants of concern on testing methodology and RAT screening efficacy

The lateral flow test technology used for RATs show a positive result via a chemical reaction that produces a colour (or fluorescence) when immobilised antibodies bind to specific antigens.[66] The continuing emergence of new SARS-Co-2 variants of concern (VoC) have raised questions about the suitability of rapid antigen tests to detect such proteins. Performance of RATs on variants of concern is largely dependent on whether the RAT detects the nucleocapsid (N) or spike (S) protein. RATs apply antibodies to the N and less commonly, the S antigen as capture molecules.[67] Mutations in the S antigen are most prevalent in SARS-CoV-2 variants; however most commercial SARS-CoV-2 antigen tests target the N antigen.[68]

There is little published literature evaluating the impact of the currently dominant delta variant on the efficacy of RATs. However, a study into the impact the alpha and beta variants on RAT test performance showed detection to be comparable to the non-VoC strain.[69] One recently published study assessing Abbott BinaxNOW COVID-19 Ag Card (BinaxNOW) RAT determined that it was able to detect all major variants of concern, including delta at Ct values less than or equal to 27.[56] Continued clinical validation of individual tests against each VoC is critical for ongoing evaluation of RAT accuracy.[69,70]

PATH, an international non-government organisation, is continually compiling publically available data on the target proteins for available SARS-CoV-2 antigen tests. The information is sourced from product inserts, webpages, and outreach to manufacturers. This group has collated data on whether RATs available worldwide target the N, S or both antigens and if the manufacturer claims detection of the delta variant (including if the claim has been verified). The dashboard and list of claims are available here.[68]

Approach to the review

International reports and scientific briefs that evaluated the utility of POC and at-home RAT to detect COVID-19 in different settings and levels of community transmission were reviewed to identify the principal considerations for implementation.

Other considerations

In the course of developing this advice, NCHRAC identified the following considerations that were out of scope for this advice, but are important and related considerations:

- Resourcing and availability of RAT
- Economic evaluation of implementing RAT

Attachments

Appendix 1: Australian pilot programs – rapid antigen testing

References

1 Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK - Technical report. *European Centre for Disease Prevention and Control* (19 Nov 2020).

2 Hodges, E. *et al.* Use of Rapid Antigen Testing for SARS-CoV-2 in Remote Communities Yukon-Kuskokwim Delta Region, Alaska. Morbidity and Mortality Weekly Report 1120 MMWR *US Department of Health and Human Services/Centers for Disease Control and Prevention* (August 20, 2021. Vol. 70. No. 33).

3 *Interim guidance on the use of rapid antigen detection tests for the identification of SARS-CoV-2 infection, Government of Canada*, <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/use-rapid-antigen-detection-tests.html> (2021).

4 Basile, L. *et al.* Diagnostic Performance of Ag-RDTs and NAAT for SARS-CoV2 Identification in Symptomatic Patients in Catalonia. *Viruses* **13**, doi:10.3390/v13050908 (2021).

5 Bianco, G. *et al.* Evaluation of an antigen-based test for hospital point-of-care diagnosis of SARS-CoV-2 infection. *J Clin Virol* **139**, 104838, doi:10.1016/j.jcv.2021.104838 (2021).

6 Bohn, M. K. *et al.* IFCC interim guidelines on rapid point-of-care antigen testing for SARS-CoV-2 detection in asymptomatic and symptomatic individuals. *Clin Chem Lab Med* **59**, 1507-1515, doi:10.1515/cclm-2021-0455 (2021).

7 Thakur, P. *et al.* Utility of Antigen-Based Rapid Diagnostic Test for Detection of SARS-CoV-2 Virus in Routine Hospital Settings. *Lab Med*, doi:10.1093/labmed/lmab033 (2021).

8 Turcato, G. *et al.* Clinical application of a rapid antigen test for the detection of SARS-CoV-2 infection in symptomatic and asymptomatic patients evaluated in the emergency department: A preliminary report. *J Infect* **82**, e14-e16, doi:10.1016/j.jinf.2020.12.012 (2021).

9 Möckel, M. *et al.* SARS-CoV-2 antigen rapid immunoassay for diagnosis of COVID-19 in the emergency department. *Biomarkers* **26**, 213-220, doi:10.1080/1354750x.2021.1876769 (2021).

10 Crozier, A., Rajan, S., Buchan, I. & McKee, M. Put to the test: use of rapid testing technologies for covid-19. *Bmj* **372**, n208, doi:10.1136/bmj.n208 (2021).

11 *Advice for high-risk settings. ACT Governement* <https://www.covid19.act.gov.au/stay-safe-and-healthy/advice-for-high-risk-settings> (2021).

12 *NSW Health quarantine worker surveillance and testing program*, <https://www.health.nsw.gov.au/Infectious/covid-19/Pages/saliva-testing.aspx#faqs> (

13 *Saliva testing adds another protective layer in pandemic defence*, <https://www.health.nsw.gov.au/Infectious/covid-19/update/Pages/saliva-testing.aspx> (Thursday 4 February 2021).

14 Smith, R. L. *et al.* Longitudinal Assessment of Diagnostic Test Performance Over the Course of Acute SARS-CoV-2 Infection. *The Journal of Infectious Diseases*, doi:10.1093/infdis/jiab337 (2021).

15 PHLN STATEMENT ON USING SALIVA AS A RESPIRATORY SPECIMEN FOR SARS-CoV-2 TESTING. *Public Health Laboratory Network* (7 June 2021).

16 *Workers in healthcare, F&B, public sector must be vaccinated or do Covid-19 self-tests from Oct 1*, <https://www.straitstimes.com/singapore/workers-in-healthcare-fb-public-sector-must-be-vaccinated-or-do-covid-19-self-test-from> (6 August 2021).

17 Novel coronavirus (COVID-19) standard operating procedure. Use of lateral flow devices for asymptomatic staff testing at vaccination sites. https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/11/C1388_Use-of-lateral-flow-devices-for-asymptomatic-staff-testing-at-vaccination-sites-standard-operating-proce.pdf. *NHS* (8 September 2021, Version 3).

18 Novel coronavirus (COVID-19) standard operating procedure. Use of lateral flow devices for asymptomatic staff testing For SARS CoV-2 in all NHS Staff. https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/11/C1385_Use-of-lateral-flow-devices-for-SARS-CoV-2-in-all-NHS-staff-standard-operating-procedure_September_v2.pdf. *NHS* (8 September 2021, Version 2).

19 COVID-19: management of staff and exposed patients or residents in health and social care settings. Public Health England. (23 August 2021).

20 *Media Statement - Tuesday, 31 August 2021 - COVID-19 Positive cases in custody*, <https://www.justicehealth.nsw.gov.au/about-us/news-and-events/media-statements> (31 August 2021).

21 World first rapid COVID-19 testing to protect Aboriginal and Torres Strait Islander communities - Media release. *Ministers Department of Health* (16 April 2020).

22 Mardian, Y., Kosasih, H., Karyana, M., Neal, A. & Lau, C. Y. Review of Current COVID-19 Diagnostics and Opportunities for Further Development. *Front Med (Lausanne)* **8**, 615099, doi:10.3389/fmed.2021.615099 (2021).

23 Speers, D. Role of testing for the COVID-19 response in Aboriginal, Torres Strait Islander and regional populations. *MICROBIOLOGY AUSTRALIA* **42**, doi:https://doi.org/10.1071/MA21007 (2021).

24 *Rapid Antigen Testing - Framework and Standard Operating Procedure*, <https://www.nsw.gov.au/sites/default/files/2021-09/209659_RAS%20Framework%20and%20Standard%20Operating%20Procedure%20Aug21%20v6_0.pdf> (Ausust 2021).

25 *CBC News*, <https://www.cbc.ca/player/play/1856970307635> (2021).

26 *Provincial Antigen Screening Program: Information Document.*, <https://www.ontariomidwives.ca/sites/default/files/COVID-19%20ID%20Resources/1.%20Provincial%20Antigen%20Screening%20Program%20Information%20Document%202021-03-22%20F.pdf > (Accessed 31 August 2021).
27 *COVID-19 SA Border Requiremetns Essential Travellers. Government of South Australia*, <https://www.dit.sa.gov.au/covidborderinfo> (24 September 2021).
28 *Operational protocol for freight movements entering Queensland*, <https://www.health.qld.gov.au/system-governance/legislation/cho-public-health-directions-under-expanded-public-health-act-powers/border-restrictions/freight-services-protocol> (18 August 2021).
29 *Transport for NSW response to COVID-19 for the freight industry*, <https://www.transport.nsw.gov.au/operations/freight-hub/transport-for-nsw-response-to-covid-19-for-freight-industry#FAQs> (17 September 2021).
30 *National Heavy Vechicle Regulator. Coronavirus (COVID-19) response*, <https://www.nhvr.gov.au/about-us/coronavirus-response> (24 September 2021).
31 Wake, R. Rapid Antigen Testing in WA. Screening of Transport, Freight and Logistics Drivers at WA Road Borders. *Power Point Presentation*.
32 COVID-19 rapid antigen testing and screening in schools. *NSW Health* (2021).
33 Jung, C. *et al.* Diagnostic Accuracy of SARS-CoV-2 Antigen Detection Test in Children: A Real-Life Study. *Front Pediatr* **9**, 647274, doi:10.3389/fped.2021.647274 (2021).
34 L'Huillier, A. G. *et al.* Diagnostic Accuracy of SARS-CoV-2 Rapid Antigen Detection Testing in Symptomatic and Asymptomatic Children in the Clinical Setting. *J Clin Microbiol* **59**, e0099121, doi:10.1128/jcm.00991-21 (2021).
35 Ford, L. *et al.* Antigen Test Performance Among Children and Adults at a SARS-CoV-2 Community Testing Site. *J Pediatric Infect Dis Soc*, doi:10.1093/jpids/piab081 (2021).
36 Young, B. C. *et al.* [PRE-PRINT] A cluster randomised trial of the impact of a policy of daily testing for contacts of COVID-19 cases on attendance and COVID-19 transmission in English secondary schools and colleges. *medRxiv*, 2021.2007.2023.21260992, doi:10.1101/2021.07.23.21260992 (2021).
37 Revollo, B. *et al.* Same-day SARS-CoV-2 antigen test screening in an indoor mass-gathering live music event: a randomised controlled trial. *The Lancet Infectious Diseases* **21**, 1365-1372, doi:10.1016/S1473-3099(21)00268-1 (2021).
38 *PRE-EVENT TESTING (PET) Singapore Ministry of Health*, <https://www.moh.gov.sg/covid-19/statistics/pet> (17 September 21).
39 Kiang, M. V. *et al.* Routine asymptomatic testing strategies for airline travel during the COVID-19 pandemic: a simulation study. *Lancet Infect Dis* **21**, 929-938, doi:10.1016/s1473-3099(21)00134-1 (2021).
40 *Travel abroad from England during coronavirus (COVID-19)*, <https://www.gov.uk/guidance/travel-abroad-from-england-during-coronavirus-covid-19 > (19 July 2021).
41 Yokota, I., Shane, P. Y. & Teshima, T. Logistic advantage of two-step screening strategy for SARS-CoV-2 at airport quarantine. *Travel Med Infect Dis* **43**, 102127, doi:10.1016/j.tmaid.2021.102127 (2021).
42 *Considerations for quarantine of contacts of COVID-19 cases. World Health Organization (2020)*, <https://www.who.int/publications/i/item/considerations-for-quarantine-of-individuals-in-the-context-of-containmentfor-coronavirus-disease-(covid-19)> (

43 *Malaysians in Singapore buoyed by home quarantine option, but approvals less straightforward than expected*, <https://www.channelnewsasia.com/asia/malaysia-singapore-home-quarantine-approvals-less-straightforward-covid-19-2151966> (03 Sep 2021).
44 *FAQS - FOR PERSONS UNDER QUARANTINE (PUQ) ON HOME QUARANTINE ORDER (HQO)*, <https://www.moh.gov.sg/covid-19/general/faqs/faqs---for-persons-under-quarantine-(puq)-on-home-quarantine-order-(hqo)-who-are-fully-vaccinated> (16 Sep 2021).
45 *3. Quarantine measures (New). Ministry of Foreign Affairs of Japan*, <https://www.mofa.go.jp/ca/fna/page4e_001053.html#section3> (August 16, 2021).
46 *The Japan Times* <https://www.japantimes.co.jp/news/2021/09/09/national/japan-quarantine-vaccinated-travelers-reduced/ > (9 September 2021).
47 *Australian Government Department of Health, Therapeutic Goods Administration, COVID-19 rapid antigen point-of-care tests*, <https://www.tga.gov.au/covid-19-rapid-antigen-point-care-tests> (10 September 2021).
48 García-Fiñana, M. & Buchan, I. E. Rapid antigen testing in COVID-19 responses. *Science* **372**, 571-572, doi:10.1126/science.abi6680 (2021).
49 Pavelka, M. *et al.* The impact of population-wide rapid antigen testing on SARS-CoV-2 prevalence in Slovakia. *Science* **372**, 635-641, doi:10.1126/science.abf9648 (2021).
50 *Coronavirus (COVID-19) testing before you travel to England. UK Department for Transport*, <https://www.gov.uk/guidance/coronavirus-covid-19-testing-for-people-travelling-to-england#when-to-take-your-test > (
51 *Liverpool Covid-SMART pilot evaluation*, <https://www.liverpool.ac.uk/coronavirus/research-and-analysis/covid-smart-pilot/> (2021).
52 Rapid antigen testing kits for high-risk NSW Local Government Areas - Media release. *Australian Government Department of Health* (27 August 2021).
53 Lindner, A. K. *et al.* Diagnostic accuracy and feasibility of patient self-testing with a SARS-CoV-2 antigen-detecting rapid test. *J Clin Virol* **141**, 104874, doi:10.1016/j.jcv.2021.104874 (2021).
54 Lindner, A. K. *et al.* Head-to-head comparison of SARS-CoV-2 antigen-detecting rapid test with self-collected nasal swab versus professional-collected nasopharyngeal swab. *Eur Respir J* **57**, doi:10.1183/13993003.03961-2020 (2021).
55 Harmon, A. *et al.* Validation of an At-Home Direct Antigen Rapid Test for COVID-19. *JAMA Netw Open* **4**, e2126931, doi:10.1001/jamanetworkopen.2021.26931 (2021).
56 Frediani, J. K. *et al.* Multidisciplinary assessment of the Abbott BinaxNOW SARS-CoV-2 point-of-care antigen test in the context of emerging viral variants and self-administration. *Sci Rep* **11**, 14604, doi:10.1038/s41598-021-94055-1 (2021).
57 *Regular rapid lateral flow coronavirus (COVID-19) tests. NHS*, <https://www.nhs.uk/conditions/coronavirus-covid-19/testing/regular-rapid-coronavirus-tests-if-you-do-not-have-symptoms/> (2021).
58 *Nationwide Distribution of Antigen Rapid Test (ART) Self-Test Kits*, <https://www.moh.gov.sg/covid-19/selftestart> (
59 *Australian Government Department of Health, Therapeutic Goods Administration, COVID-19 rapid antigen point-of-care and self-tests*, <https://www.tga.gov.au/covid-19-rapid-antigen-point-care-and-self-tests> (27 September 2021).
60 *Australian Government Department of Health, Therapeutic Goods Administration, COVID-19 test kits included in the ARTG for legal supply in Australia*,

<https://www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia> (12 August 2021).

61 Williamson, D. & Lewin, S. *Rapid antigen testing isn't perfect. But it could be a useful part of Australia's COVID response. The Conversation*, <https://theconversation.com/rapid-antigen-testing-isnt-perfect-but-it-could-be-a-useful-part-of-australias-covid-response-164873> (

62 Schwartz, K. L., McGeer, A. J. & Bogoch, I. I. Rapid antigen screening of asymptomatic people as a public health tool to combat COVID-19. *Canadian Medical Association Journal* **193**, E449, doi:10.1503/cmaj.210100 (2021).

63 Mina, M. J., Parker, R. & Larremore, D. B. Rethinking Covid-19 Test Sensitivity — A Strategy for Containment. *New England Journal of Medicine* **383**, e120, doi:10.1056/NEJMp2025631 (2020).

64 *Centers for Disease Control and Prevention. Transcript for the CDC telebriefing update on COVID-19*, <https://www.cdc.gov/media/releases/2020/t0625-COVID-19-update.html)> (June 25, 2020).

65 Larremore, D. B. *et al.* Test sensitivity is secondary to frequency and turnaround time for COVID-19 screening. *Sci Adv* **7**, doi:10.1126/sciadv.abd5393 (2021).

66 Kumar, M. *et al.* FnCas9-based CRISPR diagnostic for rapid and accurate detection of major SARS-CoV-2 variants on a paper strip. *Elife* **10**, doi:10.7554/eLife.67130 (2021).

67 Shaffaf, T. & Ghafar-Zadeh, E. COVID-19 Diagnostic Strategies Part II: Protein-Based Technologies. *Bioengineering (Basel)* **8**, doi:10.3390/bioengineering8050054 (2021).

68 *Implication of variants on COVID-19 antigen test detection. PATH Diagnostics*, <https://www.path.org/programs/diagnostics/covid-dashboard-implication-variants-covid-19-antigen-test-detection/> (

69 Jungnick, S. *et al.* Detection of the new SARS-CoV-2 variants of concern B.1.1.7 and B.1.351 in five SARS-CoV-2 rapid antigen tests (RATs), Germany, March 2021. *Euro Surveill* **26**, doi:10.2807/1560-7917.Es.2021.26.16.2100413 (2021).

70 Mina, M. J., Parker, R. & Larremore, D. B. Rethinking Covid-19 Test Sensitivity - A Strategy for Containment. *N Engl J Med* **383**, e120, doi:10.1056/NEJMp2025631 (2020).

Appendix 1: Australian Pilot Programs - Rapid Antigen Testing

Rapid Antigen Testing has not been used extensively in Australia for COVID-19; however, pilots have been used under the following strategies (for examples see Table A1):

- Focused Symptomatic Screening
- Protective Screening of High-Risk Populations
- Testing to Enable Activities

In these conditions rapid antigen tests have been used by some Australian employers, as they have been adopted for use in a variety of sectors and industry (see also Table A1). Many of the uses of rapid antigen testing have been for business continuity, to prevent entry of infected people into facilities and to prevent exposure to workers and/or patients (and the associated loss of workforce).

Figure A1. Model of Rapid Antigen Testing in Australia

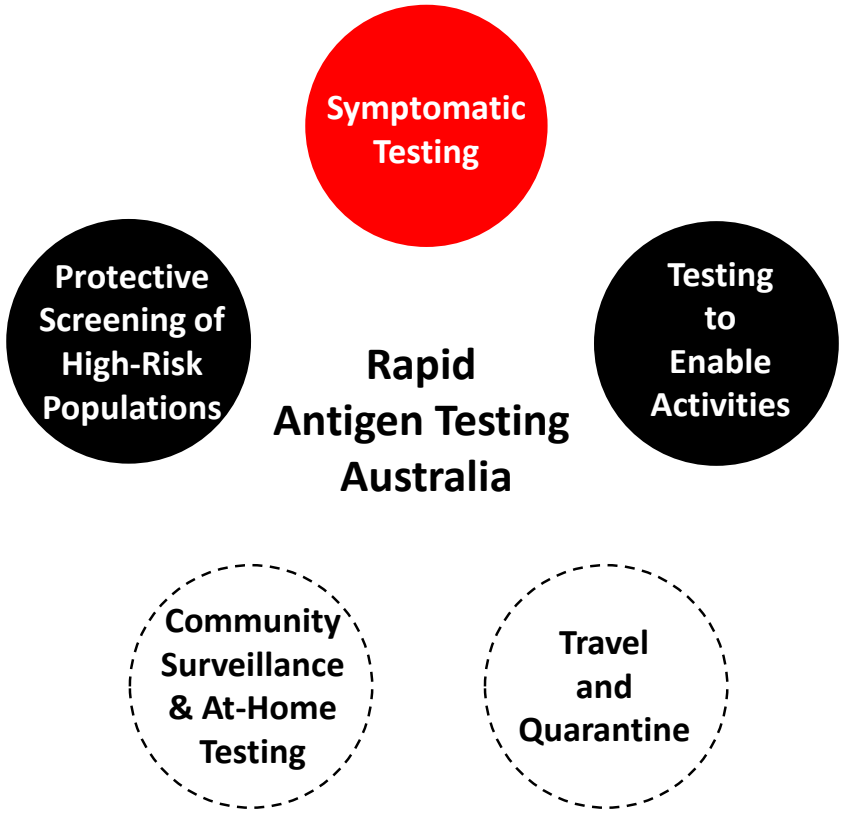

Figure A1. The model of rapid antigen testing (RAT) in Australia. Filled circles indicate scenarios where RAT has been trialled within Australia. The black and white dotted open circles indicated areas where RATs are being used elsewhere in the world and offers possible expansion opportunities for Australia. Red indicates 'Symptomatic Screening' from trails run in pharmacies (evaluations not forthcoming). 'Protective Screening of High Risk Populations' includes vulnerable population's examples as such as those in aged care settings, prisons and quarantine workers. The 'Test to Enable Activities' includes workforce examples such as: construction industries, mining industries and performing arts company (see Table A1).

Further expansion for the use of rapid antigen testing is likely in Australia with development in the use of:

- Travel and Quarantine
- Community Surveillance

Trials have been piloted for use in quarantine settings such as in Howards Springs for returning Australians. The rationale for the transfer to PCR testing under these conditions is outlined below.

Table A1. Pilots or RAT in Australia Government and Non-Government

Pilot	Locations	Outcome	Organiser	Notes
Symptomatic Testing – *Confirm case diagnosis and rapidly trace contacts*				
COVID-19 Testing in Pharmacies Pilot Project	10 metropolitan pharmacies may take part in the pilot	Build the network to more than 60 COVID-19 testing locations Screening for COVID-19 in people experiencing mild symptoms of COVID-19	SA Health, and SA Pathology	Not for general public attendance – Screening for eligible clients- mild COVID symptoms. SA Health not promoting the pharmacy-based service.
COVID-19 Testing in Pharmacies Pilot Project	Townsville, Cairns, West Moreton and Metro North health regions		Queensland Health	There is disagreement between the Guild lobby and the Pharmaceutical Society of Australia (PSA). The PSA has called on the Queensland Government to halt planning for the trial, given the new COVID cluster emerging in the state.
Protective Screening of High-Risk Populations – *Regular testing to find cases in high risk settings*				
NSW Government – Legislation	Workers who live in 12 Sydney local government areas			Hotspot LGA's individuals must have one dose of the Covid-19 vaccine or a RAT to work outside their area.
NSW Justice Health (Prisons)	Correctional Centre's: Parklea Silverwater Bathurst	State-wide prison lockdown to control outbreaks. Manage people	NSW Justice Health	Introduced in response to an outbreak in NSW prison. Staff tested on entry 100 per hour. Supervised self-testing – manual recording.

Pilot	Locations	Outcome	Organiser	Notes
		with highly vulnerable health and conditions.		
Rapid Antigen Testing trial at Whiddon Easton Park[a]	Whiddon • 4 x Care homes • 10-15min per test • Trial cost $95,000-	Reduces risk of COVID-19 outbreak in aged care facilities	Respond Global	Daily RAT of employees, which has continued whilst community transmission of COVID-19 remains high. Total of 5,180 antigen tests were conducted over the 2 week period, with 370 staff tested daily – there were no positive results during this time.
Residential aged care facilities in Greater Sydney	Uniting Bankstown Aged Care Facility	Expands on trial at the Whiddon Residential Aged Care Facility in Glenfield	Department Health contracted Respond Global	
Rapid antigen testing in aged care	Areas (LGAs) of concern across Sydney and Western NSW	Providers responsible to provide infrastructure, resources to support screening.	The pilot has been informed by a trial undertaken by the Whiddon Group, in partnership with Respond Global. The Nous Group will evaluate Phase 1 of the pilot.	Residential aged care (including MPS and NATSIFAC).Home care, and Services delivered through the Commonwealth Home Support Program. Phase 1 (4 weeks) involves 10 participating sites in the greater Sydney region. Phase 2 (12 weeks) will be informed by Phase 1 and is expected to involve aged care facilities within Greater Sydney. The pilot will not include aged care residents.
Northern Territory – Howard Springs	Staff whose employment involves daily/regular contact with a person in quarantine Provision of Howard Springs International	A pilot was conducted at Howard Springs (total of ~30,000 tests ~3 false positives over 3 months[b]) using RAT. Reverted from RAT to saliva	Respond Global	RAT -was only used on staff and not used on those undergoing quarantine, who had standard PCR testing.

[a] Rapid Antigen Testing trial at Whiddon Easton Park: An Evaluation (2021). Accessed 2 September 2021 https://www.whiddon.com.au/wp-content/uploads/2021/08/Whiddon-Glenfield-Rapid-Antigen-Test-Trial-July-2021-FV.pdf

[b] COLYER S. (2021). Rapid antigen testing key for asymptomatic screening. MJA Insight. Issue 31 / 23 August 2021 https://insightplus.mja.com.au/2021/31/rapid-antigen-testing-urgently-needed-for-asymptomatic-screening/

Pilot	Locations	Outcome	Organiser	Notes
	Quarantine - COVID-19 Rapid Antigen Testing Kits Cost $80,279.	PCR after advice from PHLN and AHPPC.		
Testing to Enable Activities – *Enable return to otherwise restricted activities of health, social, education, economic*				
Victorian Government - Doherty Institute pilot in March 2021	3 x Melbourne Hospitals – The Royal Melbourne Hospital, Austin Health and Monash Health	Tests performed best first few days after symptom onset	Victorian Government - Doherty Institute	Published results Conducted during a period of low COVID-19 prevalence
Opera Australia	Sydney Opera House Opera Australia headquarters in Surry Hills,	COVID-safe work environment & significantly reduce the risk of coronavirus transmission	Hemisphere Biosecurity	First performing arts company in Australia to introduce rapid antigen testing, as a key element of their program to keep performers and staff safe.
School Screening – NSW announcement		Local conditions will indicate the levels of restrictions in schools		
John Holland Screening	Locations in NSW •Sydney Football Stadium •Sydney Metro Tunnel Stations Excavations	Sustain work output	John Holland	Voluntary testing Work spaces separated into zones and entry requires check in with QR code.
Construction workers NSW Construction workers Victoria		Requirement for construction site in NSW if not vaccinated Not using RAT on site testing	NSW Health	50% of staff on site. 25% of Staff on site. Permits required
International Airlines – Qantas - TBC		Surveillance of workforce		PCR required 72 hours prior. Air Canada offering at home testing – telehealth for first test

Pilot	Locations	Outcome	Organiser	Notes
Mining – Western Australia[c]	Rio Tinto	Sustain workforce-privilege to keep working. Protect health and safety	Rio Tinto	Specific approval by WA Chief Health Officer. Testing FIFO workers: • Questionnaire • Temperature • RAT 1 in 3,500 false positives Screening voluntary people could decline. Max # conducted at Perth airport ~2,000 tests /one day
Mining – Western Australia[d]	Fortescue Metals Group	COVID-19 testing blitz revealed no new cases among workers	Fortescue Metals Group	Implement screening programs, includes PCR testing for all fly-in, fly-out team members and mandatory temperature testing
Banking Industry Westpac Commonwealth Bank	Canterbury-Bankstown & Concord Voluntary testing in Sydney hotspots	Easier for employees "to balance the demands of work, home life and being in lockdown, while prioritising their health and getting vaccinated".		Testing in branch, using a nostril swab by medical professional Vax centres & RAT Testing program to be available to staff in more Westpac workplaces two-week trial
Long haul freight and transport workers	South Australia, Western Australian and Northern Territory	WA standard operating procedures, results log and QC log developed	SA, WA and NT public health	WA presented experience of RAT implementation at 2 border sites – Eucla and Kununurra. SA are starting late September in 2 crossings – Yamba and Taylor Bend.

[c] Western Australian Government. (2020) Prohibition on the use of Rapid Antigen Testing. "*directions is to prohibit a person from using a SARS-Co V-2 rapid antigen test ("Rapid Antigen Test"} as an acute illness diagnostic tool for COVID-19, as their use may adversely affect the prevention, control and abatement of the serious public health risk present by COVID-19*." 19 October 2020.

[d] Western Australian Government. (2020) Prohibition on the use of Rapid Antigen Testing. "*directions is to prohibit a person from using a SARS-Co V-2 rapid antigen test ("Rapid Antigen Test"} as an acute illness diagnostic tool for COVID-19, as their use may adversely affect the prevention, control and abatement of the serious public health risk present by COVID-19*." 19 October 2020.
"As at 12pm, 5 August 2021, over 1,200 PCR tests and 850 rapid antigen tests have been completed across Fortescue's operational sites" https://www.watoday.com.au/national/western-australia/it-doesn-t-fit-experts-question-whether-wa-s-fifo-coronavirus-case-is-a-false-positive-20210805-p58gb8.html Despite the directive fly-in, fly-out workers have these tests prior to boarding planes.
https://www.afr.com/policy/health-and-education/silly-rules-on-rapid-antigen-tests-don-t-help-business-20210822-p58kuv
https://company-announcements.afr.com/asx/fmg/22148218-f5ab-11eb-b760-a6c58728ef41.pdf

Figure 2A. Possible model for Rapid Antigen Testing within the test, trace, isolate, quarantine' (TTIQ) framework

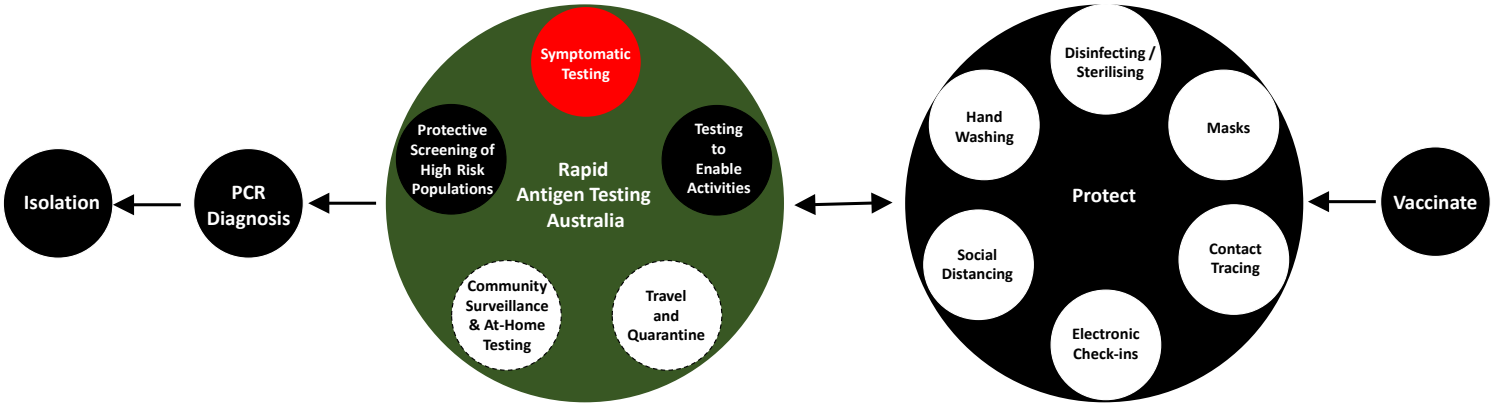

Figure 2A. Schematic model that illustrates “test, trace, isolate, quarantine” (TTIQ) and where the role of rapid antigen testing may be in Australian conditions.