COVID-19 Testing Policy Positions

Roche Diagnostics Australia

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About Roche

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Roche policy positions on COVID-19 Testing in Australia

Purpose of document

This document represents Roche Diagnostics Australia's *(hereby referred to as Roche)* policy positions on SARS-CoV-2 testing which are based on an overview and analysis of the current national and international landscape together with supporting evidence. This document has largely focussed on the use of rapid antigen tests given their importance, particularly with the emergence of more rapidly transmissible variants of SARS-CoV-2 *(the virus)* and recent announcements outlining a transition plan to living with the virus (COVID-Normal). In the future, Roche will develop further policy positions on the use of emerging testing technologies, particularly serology tests in the context of continuing vaccination efforts in Australia.

We hope this document will assist policy makers in informing changes to the SARS-CoV-2 testing arrangements to support a successful transition to COVID-Normal.

NOTE: References to COVID-19 in this document refer to infection with SARS-CoV-2 rather than the disease caused by the virus. This aligns with the terminology used in the references sourced for this document, which have adopted that terminology in lieu of naming the virus.

Executive summary

Australia has been a global leader and one of the best responding countries to the SARS-CoV-2 pandemic with a highly successful suppression strategy that resulted in a very low prevalence of infection (i.e. the number of infected individuals in a population). Effective and widespread testing played a key role in this success.

Roche is proud of its significant contribution, which included the introduction of the first automated commercial real time polymerase chain reaction (RT-PCR) tests in Australia in the same month that the World Health Organisation (WHO) declared the pandemic, followed by the development of other testing technologies to broaden the pandemic management arsenal. We have partnered with the Australian Government to ensure continuity of supply, and with laboratories and clinicians to enable scale up of testing capacity. We will continue to support our partners as required.

Since the beginning of the pandemic, Roche and other diagnostic companies have continued to develop testing modalities to complement the existing gold standard tests (laboratory-based RT-PCR). In the rapidly evolving epidemiological context, nationally and internationally, it is critical that Australia leverages the benefits offered by the full range of testing technologies to be able to rapidly and flexibly respond to emerging challenges. This is because all tests, including laboratory-based RT-PCR, have limitations and diversity of testing modalities can help fill unmet needs arising from those limitations.

On 2 July 2021, the Prime Minister announced a four stage National Plan to Transition Australia's National COVID Response (The Plan). Under The Plan, suppression of the virus will continue for the first two stages followed by management of the virus in the community, culminating in no lockdowns (which have been estimated to cost the economy $4 billion per week when occurring

at a national level[1]) and free movement across national and international borders subject to vaccination. Testing will continue to remain a key feature across all stages.[2]

Rapid antigen tests are a key testing technology currently underutilised in Australia, which can play a fundamental role in supporting the suppression and management phases outlined in The Plan. However, in order to do so, existing barriers to broader use of these tests need to be addressed. Currently, public health guidelines do not recommend the use of these tests in most circumstances and the Therapeutic Goods Administration (TGA) has imposed regulatory limitations on the supply and use of these tests. A review of these will be required to enable Australia to leverage the key benefits of rapid antigen tests.

International experience
Internationally, many countries including Singapore and Germany have already adopted the use of rapid antigen tests to safely re-open their countries and return to a more normal way of life. A recent study from the German experience (which adopted a staged approach to the introduction of rapid antigen testing, eventually in conjunction with vaccination) indicated that rapid antigen testing should remain part of strategies to contain COVID-19. It can substitute non-pharmaceutical interventions such as lockdowns and social distancing which reduce contacts between individuals that come at a much higher cost to individuals, society and the economy.[3]

Value proposition
Despite having a lower capacity to detect positive cases compared to laboratory-based RT-PCR, rapid antigen tests have three key attributes which make them an incredibly useful complement to laboratory-based RT-PCR in Australia by providing an additional layer of protection for individuals, businesses and the community. These are:

i. Their very high specificity (their capacity to identify individuals that are not infected)
ii. The speed of obtaining results
iii. The ease of use

These attributes mean that rapid antigen tests are useful where there is value in quickly and accurately identifying individuals who are NOT infected, with faster identification of infected individuals than is possible using laboratory-based RT-PCR tests, and where increased convenience of testing is desirable. It should be noted that tests typically perform best for excluding an infection when the pre-test probability (i.e the probability of being infected) is low (i.e. in Australia) and best for detecting an infection when the pre-test probability is high.[4] In other words, in a low prevalence setting like Australia, the confidence with which one can interpret a result to exclude infection is higher than in a high prevalence setting.

The benefits of rapid antigen testing include:

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[1] Josh Frydenberg M., 12 May 2020. Address to the National Press Club https://ministers.treasury.gov.au/ministers/josh-frydenberg-2018/speeches/address-national-press-club-canberra (accessed 5 July 2021).
[2]National Cabinet Statement, https://www.pm.gov.au/media/national-cabinet-statement-6 (accessed 5 July 2021).
[3] Gabler et al., June 2021. The Effectiveness of Strategies to Contain SARS-CoV-2: Testing, Vaccinations and Non-pharmaceutical interventions. ECONtribute. Discussion Paper No. 100 - page 1.
[4] CDC website, https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html#Interpreting-Results-of-Diagnostic-Tests (accessed 5 July 2021).

- Screening to reduce the risk of introducing or exporting the virus into and from certain settings, particularly high-risk settings to better protect vulnerable individuals, communities and workplaces and the community at large
- Screening to support a return to normal activities such as travelling and attending large entertainment and sporting events
- Enabling the rapid triaging and management of potentially positive individuals by separating them from individuals that have tested negative thereby reducing transmission and restrictions on movement of uninfected individuals
- Facilitating faster public health responses as more transmissible variants of the virus evolve
- Increasing capacity to be deployed as part of a mobile response effort to 'closed' environments such as mining sites, oil rigs, residential aged care facilities etc.
- Offering a sustainable way to help transition from a pandemic to an endemic environment
- Supporting testing compliance by making it easier for individuals to get tested, reducing time off work to get tested and avoiding the need to isolate while they wait for their results

Consequently, the use of these tests can protect public health as we progress to, and when we reach, COVID-Normal whilst:

- Minimising the risk of lockdowns
- Securing business continuity
- Supporting the recovery of sectors disproportionately impacted by the pandemic such as the tourism, education and the arts sector
- Supporting national economic recovery including by addressing critical workforce skills shortages
- Strengthening quarantine whilst allowing for more flexible risk based approaches to quarantine
- Allowing more freedom of movement nationally and internationally
- Retaining the value of surveillance data as COVID fatigue sets in and symptomatic individuals avoid testing

Use cases

Specific use cases that leverage the attributes of rapid antigen tests include:

- Testing to avoid introducing or exporting the virus into and from high-risk settings. High-risk settings include those where individuals are at higher risk of contact with the virus (e.g. quarantine), congregate settings where rapid transmission of the virus can occur (e.g. prisons) and communities with a high proportion of individuals at risk of a negative outcome from infection (e.g. aged care facilities)
- Testing at large sporting or entertainment events to reduce the risk of the event being a "super-spreader" event
- Testing international and domestic travellers to re-open borders
- Testing to allow more flexible risk-based quarantine arrangements

While Australia's approach to testing has been very successful, its testing strategy and regulatory requirements need to evolve as we progress through to COVID-Normal. Underpinning our cautious approach to the adoption of rapid antigen testing are the concerns about the performance of rapid antigen tests compared to the gold standard with respect to identifying positive cases (the sensitivity of the test), particularly in a low prevalence setting, and the variability between tests. Another further concern relates to compliance with reporting test results to support COVID-19 related surveillance activities.

Test sensitivity

In respect to sensitivity, evidence presented in this paper outlines that:

- The speed of obtaining results is more important in reducing transmission than sensitivity
- The capacity to identify positive cases can be increased by the adoption of more frequent testing regimens with rapid tests
- Frequent serial testing with rapid tests can identify more positive cases than serial monthly RT-PCR testing, is cheaper and minimises restriction on movement

As more rapid antigen tests are validated using sample types that are more convenient and less invasive to obtain (i.e. saliva or nasal vs nasopharyngeal), the acceptability of conducting more frequent testing will be improved.

Test variability

In respect of the variability of tests, all rapid tests registered for use in Australia by the TGA (including Roche's test) must meet the Australian essential principles for safety and performance of Therapeutic Goods (Medical Devices) Regulations 2002 . Concerns over variability can be addressed by the TGA publishing expanded test performance data on their website and procurement processes including performance thresholds acceptable to the purchaser. In addition, concern has been raised on the performance of tests with emerging variants. Many companies (including Roche) continuously monitor for new SARS-CoV-2 variants or mutations to ensure they are detected in both existing and new assays (be they rapid antigen tests or other test types).

The public health consequences of having false negatives is unacceptable.

All tests (including RT-PCR) with a sensitivity below 100% result in false negatives (missed cases). As rapid antigen tests have marginally lower sensitivity than RT-PCR tests, they can generate more false negative results i.e. they miss slightly more infected individuals than RT-PCR does. However, for a test with a sensitivity of 95.5%, in a low prevalence setting like Australia (prevalence of approx. 0.001%), the number of infected individuals missed would only be five individuals out of 10 million tests. Moreover, testing sensitivity can be further increased by repeating rapid antigen tests every 2-3 days, which reduces the number of missed cases. In addition, tests with faster result times can also reduce viral transmission which is a key aim of testing.

However, the key value proposition of rapid antigen tests is to rapidly identify individuals who are NOT infected by screening them prior to entering or exiting a high-risk environment or large public gathering or screening individuals within high-risk environments. When used for this purpose, the performance measure of importance is the specificity of the test i.e. how well the test performs to identify who is NOT infected. Using a test with 99.2% specificity applied to Australia's prevalence rates, 80,000 out of 10 million tests will report as false positives. However, as individuals are not actually infected, the false positive result does not have any adverse consequences for public health. Furthermore, their result can and should be confirmed by RT-PCR which can be performed using a rapid or laboratory-based test.

Therefore, despite the number of false positives associated with rapid antigen tests, they offer a valuable tool for screening, providing an additional layer of protection to the community through testing a population that is currently being missed through RT-PCR testing alone (which is only focussed on diagnosing individuals who are likely to be infected) and false positive results confirmed by RT-PCR, which would be reported for surveillance purposes.

Reporting test-related information
The use of Apps to transmit testing data and the use of telehealth services can address concerns around valuable testing data being lost to COVID-19 surveillance activities. It should be noted that Singapore, another low prevalence country, managed concerns over rapid antigen tests through a phased introduction supported by pilot programs. This could be a useful model for Australia to consider.

Testing capacity and resilience
Effective, fit for purpose and sustainable testing strategies that are supported by diverse testing technologies will be fundamental to successfully transition to COVID-Normal. From a national resilience perspective, diversifying the range of technologies available in Australia's testing arsenal and the range of suppliers together with maintaining adequate stocking levels will be important to enable the country to optimise responses at scale when required.

Despite the vaccination rollout, the need for continued testing will remain because no vaccine is 100% effective and vulnerable groups remain in the population for whom the vaccine will be ineffective.[5] Additionally, vaccinated individuals can still become infected and while they may have reduced viral loads, they could still be infectious.[6] We need to anticipate case surges and ensure we have adequate capacity and capability to manage these as Australia balances the vaccine rollout, refines quarantine arrangements and re-opens borders whilst internationally the virus continues to mutate and global vaccination efforts are at different levels of maturity.

Roche believes the actions below are required to safely and successfully transition to COVID-Normal to support public health, business continuity and the economy. These actions focus on broadening when, where and who can use rapid antigen tests; providing financial support; and promoting national testing capacity and resilience.

Policy positions:

1. The Testing Framework developed by the Public Health Laboratory Network (PHLN) and Communicable Diseases Network Australia (CDNA) be amended to support the use of rapid tests to:
    a. cover use in high-risk settings as outlined in this document
    b. strengthen quarantine arrangements
    c. support a more risk-based approach to quarantine
    d. screen international and domestic airline travellers
    e. screen individuals prior to large public gatherings
2. The Testing Framework include guidelines on standards and elements for a quality framework to support the use of rapid tests.
3. The TGA extend the supply of antigen rapid tests to other health professionals such as pharmacists who can also be trained to deliver such testing within a quality framework.
4. States / Territories which place restrictions on supply of rapid antigen tests additional to those imposed by the TGA, align with TGA provisions.
5. Funding for testing beyond laboratory-based RT-PCR be made available for use in settings aligned to the quality framework outlined in Recommendation 2.

[5] Khayat-Khoei et al., 2021. Negative anti-SARS-CoV-2 S antibody response following Pfizer SARS-CoV-2 vaccination in a patient on ocrelizumab. Journal of Neurology.
[6] Levine-Tiefenbrun et al., 2021. Initial report of decreased SARS-CoV-2 viral load after inoculation with the BNT162b2 vaccine. Nature Medicine.

6. Where the high-risk setting is publicly funded, such as quarantine or residential aged care facilities, additional funding allocations be incorporated into the operating budget.
7. Where the high-risk setting is a private sector small - medium enterprise, grant funding or tax offsets be made available to conduct frequent workplace screening.
8. The TGA collaborates with the CDNA and PHLN to explore the conditions under which the prohibition on self-testing can be lifted to align with international counterparts.
9. Government conducts pilots to support the broader use of rapid antigen tests, including self-testing.
10. The National Medicines Stockpile ensures that a reasonable diversity of testing technologies as well as a diversity of suppliers of the same testing technology are available to enable a public health response at scale.
11. The evolving role of other emerging technologies, such as serology based testing (laboratory or point of care) be reviewed in anticipation of the vaccination targets being reached by the end of the year.

Introduction:

Australia has risen to the healthcare challenges posed by COVID-19 by responding with flexibility and speed, and has demonstrated that barriers that previously existed could be overcome.

We will need to continue to respond in this way, particularly in relation to testing for SARS-CoV-2, as we move from a pandemic to an endemic setting in order to address the constantly evolving landscape both nationally and internationally around the virus, vaccination, the emergence of mutant strains which may be more transmissible or may not respond to current vaccines, and the reopening of international borders.

1. Australia's health-related response to COVID, governance and policy settings

Australia's public health response to the pandemic began on 21 January 2020 with the listing of SARS-CoV-2 as a human disease under the Biosecurity Act 2015. This effectively enabled Australian authorities to impose stringent biosecurity measures to restrict the movement of goods and persons. Restrictive measures included international border restrictions and closures and the introduction of quarantine arrangements.[7]

The Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19) guided public health measures that were progressively introduced in response to the outbreak. These measures included the use of personal protective equipment, social distancing, quarantine in various settings (hotels, home, healthcare facilities) for those who may have come into contact with the virus, in addition to testing, contact tracing and active surveillance initiatives. A national lockdown was announced on 24 March 2020 whereby Australians were encouraged to work from home and only leave the house for essential activities in order to stop community transmission of the virus, followed by a gradual easing of restrictions as transmission was controlled and public health measures bolstered.

Following an extensive period after a viral suppression strategy, on 2 July 2021, the Prime Minister announced a four stage national plan to transition Australia to COVID-Normal. Under the Plan, the virus will continue to be suppressed for the first two phases followed by management of the virus in the community culminating in no lockdowns and free movement across national and international borders subject to vaccination. Testing will continue to remain a key feature across all phases.[2]

The objective of the COVID-19 suppression strategy is to have no community transmission.[8] In order to achieve this objective, which accepts that outbreaks remain a risk, all new cases of infection:

- occur among contacts of known cases or arrivals from overseas in quarantine
- have the source rapidly identified
- are not part of unrecognised chains of transmission in the community.[9]

The effective suppression of COVID-19 relies on the ability to rapidly identify and control clusters and outbreaks, particularly among vulnerable populations and in high-risk settings.[10]

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[7] Higginson et al., 2020. COVID-19: The need for an Australian economic pandemic response plan. Health Policy and Technology.

[8] Communicable Diseases Network Australia and Public Health Laboratory Network, Feb 2021. Testing Framework for COVID-19 in Australia. Page 2.

[9] CDNA, April 2021. Australian National Disease Surveillance Plan for COVID-19. Page 2.

[10] CDNA, April 2021. Australian National Disease Surveillance Plan for COVID-19. Page 7.

In terms of moving to a management phase, it can reasonably be expected that ongoing surveillance, quarantine, testing, contact tracing with a diminishing reliance on lockdowns to contain local outbreaks, will still be required to protect vulnerable individuals. This is because, despite the vaccination rollout, no vaccine is 100% effective and vulnerable groups remain in the population for whom the vaccine will be ineffective.[5] Additionally, vaccinated individuals can still be infected and while they may have reduced viral loads, they could still be infectious.[6]

Australia's public health response has been extremely successful with 30,460 cases and 910 deaths reported for Australia as of 27 June 2021 (out of over 180 million cases and ~ 4 million deaths reported worldwide).[11] Australia's prevalence of SARS-CoV-2 since the start of the pandemic to 25 June 2021 is very low, at 0.001% (or 1192 positive cases per 1 million people).[12]

The impact of COVID-19 on the economy has been significant, with a predicted deficit of $161 billion for 2020-21 (reducing over the next 4 years to $57 billion by 2024-25) and net debt increasing to around $1 trillion in 2025.[13] Furthermore, some industry sectors have been much more adversely impacted by the pandemic than others as a consequence of the measures introduced to protect public health, including the tourism, education, hospitality and arts sectors which make a significant contribution to the economy.[14]

In May 2020, the Treasurer noted that a full lockdown could result in losses of more than $4 billion per week to the economy (including $1.4 billion to NSW and $1 billion to Victoria).[1] However, a study in the UK notes that the economic cost of a lockdown is lower than that of an uncontrolled pandemic.[15]

Governance of the health management of COVID-19 in Australia

Under the Australian Health Sector Emergency Response Plan For Novel Coronavirus 2019, the Australian Health Protection Principal Committee (AHPPC) - which comprises of all state and territory Chief Health Officers and the Australian Chief Medical Officer - provides advice to National Cabinet on policy and implementation relating to the national health sector response.

The AHPCC oversees the Public Health Laboratory Network (PHLN) and Communicable Diseases Network Australia (CDNA). The PHLN advises on best public health pathology practice and develops guidelines for detection and monitoring of notifiable infectious diseases. The CDNA develops policy and strategy on the prevention and control of communicable disease and in the context of COVID-19 provides leadership in surveillance, the analysis of epidemiological information and strategies related to COVID-19 management respectively. Other Committees with COVID-19 health-related responsibilities also report to the AHPCC.

The CDNA has released the COVID-19 National Guidelines for public health units.[16] These Guidelines outline the national minimum standards for surveillance, laboratory testing and

[11] John Hopkins University Coronavirus resource Centre Global Map, https://coronavirus.jhu.edu/map.html (accessed 27 June 2021).
[12] Australia: Coronavirus Pandemic Country Profile, https://ourworldindata.org/coronavirus/country/australia - (accessed 29 June 2021).
[13] Budget 2021-22 – Securing Australia's Recovery Budget Overview, https://budget.gov.au/2021-22/content/overview.htm#one (accessed 25 June 2021).
[14] Australian Government. Framework for National Reopening, Oct 2020.
[15] MacIntyre, 2021. Navigating post-vaccine COVID-19 futures in the health and economic context. The Lancet.
[16] Coronavirus Disease 2019 (COVID-19) CDNA National Guidelines for Public Health Units, Ver 4.7, June 2021.

contact management for COVID-19, noting that jurisdictions may implement policies which exceed these guidelines based on local epidemiological context.

Additional Guideline[15] which informs COVID-19 management in Australia include the following:

- the Testing Framework for COVID-19 in Australia (February 2021) which outlines a national framework for testing which jurisdictions can fit to their local circumstances;
- The CDNA National Guidelines for the Prevention, Control, and Public Health Management of COVID-19 Outbreaks in Residential Aged Care Facilities in Australia
- The CDNA National Guidelines for remote Aboriginal and Torres Strait Islander Communities for COVID-19
- the Australian National Disease Surveillance Plan for COVID-19 (April 2021) which outlines the approach to surveillance for the disease and the virus

The PHLN has established a Working Group on Emerging SARS-CoV-2 Testing Technology to advise on the use of emerging testing technologies in the Australian context – in both the health and non-health settings. This will inform Australia's testing strategy.[17]

2. The types of COVID-19 testing technologies

The three main types of SARS-CoV-2 tests are available in Australia are outlined below:

1. Nucleic acid RT-PCR detection tests

These tests detect genetic fragments (ribonucleic acid [RNA]) from the virus. The quantity of the genetic material in a sample is amplified using a chemical reaction (polymerase chain reaction), meaning that very minute fragments of RNA can be detected throughout an active infection but also after the patient has recovered from the virus. Therefore, positive RT-PCR tests can be indicative of an active viral infection or could be remaining RNA fragments clearing.[18]

Studies indicate that most individuals are infectious for 4-8 days post symptom onset with most transmission occurring prior to day 5[19] and therefore the short window of infectiousness is in contrast to the long window of RT-PCR positivity, which is on average for 17 days post symptom onset.[19]

RT-PCR tests can be performed in a laboratory setting or near to a patient at the point of care. These are the only SARS-CoV-2 tests listed in the Medicare Benefits Schedule (MBS) with a fee that is paid to pathologists (ranging from $50-$110).

- *Laboratory-based RT-PCR tests:*

These tests represent the gold standard for diagnosing SARS-CoV-2 due to their high accuracy in detecting infections in both symptomatic and asymptomatic individuals. In the lab, test results can be generated in around 6 hours.[20] However, the turnaround time from sample collection to notification of results can take several days given samples need to be transported to a laboratory and processed before they can be tested and the results reported. These tests and instruments are able to process numerous samples simultaneously (i.e. are high throughput).

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[17] Communicable Diseases Network Australia and Public Health Laboratory Network, Feb 2021. Testing Framework for COVID-19 in Australia. Page 3.

[18] Bullard et al., 2020. Predicting infectious SARS-CoV-2 from diagnostic samples, Clinical Infectious Diseases.

[19] Cevik et al., 2021. SARS-CoV-2, SARS-CoV, and MERS-CoV viral load dynamics, duration of viral shedding, and infectiousness: a systematic review and meta-analysis. The Lancet.

[20] NSW Health. COVID-19 Rapid Antigen Testing - Information for Consumers, April 2021, https://www.health.nsw.gov.au/Infectious/factsheets/Pages/antigen-testing.aspx (accessed 5 July 2021).

- *Rapid RT-PCR tests:*

These tests operate similarly to the laboratory tests but results are generally produced in between 20-60 minutes, within close proximity to the patient. This avoids the delays in obtaining results associated with transporting samples to a laboratory setting etc. These tests require a portable analyser at the point of care and are lower throughput. In Australia, they are being used in Indigenous regional and remote communities,[21] in residential aged care facilities during outbreaks and also for testing passengers at Sydney Airport prior to boarding.

2. Serology tests

Serology tests that are available in Australia detect antibodies to SARS-CoV-2 from blood samples i.e. they can detect if a person has had past exposure to the virus or a vaccine. Because it can take up to 2 weeks to develop a detectable level of antibodies in response to infection with the virus, these tests are of limited value in diagnosing active infections. However, they have value in informing public health measures and may be able to indicate an individual's immunity in future.

3. Rapid antigen tests

These tests are used at the point of care to detect the presence of viral proteins from the SARS-CoV-2 virus. Typically, results are available in 15-30 minutes.[22] They are slightly less sensitive than most PCR tests and, like most PCR tests, accuracy in asymptomatic individuals is also lower compared to symptomatic individuals.

These tests have relatively high sensitivity - between 80 and 97% and very high specificity at >99%.[23]
Because they detect higher viral loads, compared RT-PCR tests which detect high and low viral loads, (with low viral loads potentially being less infectious), rapid antigen tests may be more indicative of an active infection in individuals compared to RT-PCR tests. This has been demonstrated by infectivity assays, such as viral cell culture, which determine whether a sample/swab is infectious or not.[24]

Organisations using or procuring rapid antigen tests include public and private pathology services, the private sector (e.g. mining sites and Opera Australia at Sydney Opera House[25]) and Government agencies, and include testing of employees in quarantine facilities or for passengers prior to boarding at airports. These tests are less expensive than RT-PCR and costs are generally around $10 per test.

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[21] Aboriginal and Torres Strait Islander COVID-19 Point-of-Care Testing Program, https://www.covid19poct.com.au/ (accessed 5 July 2021).
[22] COVID-19 rapid antigen testing – Information for consumers, https://www.health.nsw.gov.au/Infectious/factsheets/Pages/antigen-testing.aspx (accessed 5 July 2021).
[23] Pathology Technology Australia, Oct 2020. Position Statement: COVID-19 Antigen and Point of Care Testing. Page 1.
[24] Pekosz et al., 2021. Antigen-Based Testing but Not Real-Time Polymerase Chain Reaction Correlates With Severe Acute Respiratory Syndrome Coronavirus 2 Viral Culture. Clinical Infectious Diseases.
[25] Media release, Jan 2021. Opera Australia leading the industry in COVID-safe performing practices

3. Current COVID-19 testing arrangements in Australia

As mentioned above, the CDNA and PHLN have developed a Testing Framework for Australia. The Framework prioritises groups for testing based on greatest risk and outlines the technologies which best suit the epidemiological context (i.e. the level of community transmission).[26]

The Testing Framework provide the following positions:[27]

Who and when to test:

- Symptomatic individuals should be tested irrespective of the level of community transmission
- Asymptomatic individuals who have a known recent exposure to the virus or those at higher risk of exposure through frequent, close or extended contact with the virus, should be targeted for testing unless laboratory capacity needs to be preserved
- Asymptomatic individuals in high and special-risk settings (including where disease amplification is likely or where people live or visit, who are at an increased risk of severe disease and death) should be tested but only in case of community transmission

The Testing Framework also outlines that regular asymptomatic testing targeted to staff working in COVID-19 quarantine and isolation settings who are at risk of exposure to the virus is also recommended.[28] Furthermore, it states that large-scale, non-targeted asymptomatic testing as part of the public health response is not supported as this is not epidemiologically sound or cost-effective.[29]

Testing technologies:

- Laboratory RT-PCR testing is considered the gold standard for diagnosing acute viral infection but rapid RT-PCR point of care testing is useful in settings where rapid turnaround time is required or where access to laboratory based testing is limited
- Serology based tests may be useful in settings where the results can inform public health responses

The Framework states that use of rapid antigen tests at point of care is not supported when there is no community transmission. In a public health setting, these tests are only recommended where the pre-test probability of infection is higher such as an outbreak, but all positive results must be confirmed by RT-PCR, as well as all negative results where the individual has clinical symptoms indicative of COVID-19. It also states that there is no evidence of utility in screening an asymptomatic population in low prevalence scenarios.

The Framework also makes recommendations around genomic sequencing of the virus and wastewater testing.

The National Disease Surveillance Plan sets out the information required to monitor the epidemiology of COVID-19 and Australia's public health response, which may vary across the country and over time. The Surveillance Plan includes specific considerations for Aboriginal and Torres Strait Islander peoples.[30]

[26] CDNA and PHLN, Feb 2021. Testing Framework for COVID-19 in Australia. Page 3.
[27] CDNA and PHLN, Feb 2021. Testing Framework for COVID-19 in Australia. Page 19.
[28] CDNA and PHLN, Feb 2021. Testing Framework for COVID-19 in Australia. Page 5.
[29] CDNA and PHLN, Feb 2021. Testing Framework for COVID-19 in Australia. Page 5 and 7.
[30] CDNA, April 2021. Australian National Disease Surveillance Plan for COVID-19. Pages 3, 4.

The surveillance arrangements build on the National Notifiable Diseases Surveillance System (NNDSS) which covers over 60 communicable diseases and relies on reports from laboratories, health facilities and clinicians to State and Territory communicable disease control units. Under the NNDSS, all new diagnoses of infection with SARS-CoV-2 need to be reported. The NNDSS is supported by specialised reporting of other data to assist surveillance such as the number of tests conducted in the community, the proportion that are positive, geographical distribution, demographic information and test type is also collected and reported.[31]

4. The regulatory environment for COVID tests and current use in Australia

RT-PCR tests (both point of care and laboratory-based tests) are included on the ARTG without restriction on who can use the tests. However, given some of these tests are used in conjunction with an analyser which needs to be used by trained operators or health professionals, these tests are unlikely to be used outside the healthcare professional setting.

However, inclusion of a test on the Australian Therapeutic Goods Register (the ARTG), which indicates a test is registered for use in Australia, restricts the supply of rapid antigen point of care tests and serology tests supply of these tests to the following:[32]

- accredited pathology laboratories
- registered medical practitioners
- healthcare professionals (medical practitioners or registered / enrolled nurses) in residential and aged care facilities
- The Commonwealth, State or Territory Health Departments or any agencies acting on their behalf (such as Primary Health Networks, Correctional Facilities)

Under these conditions, tests can be supplied to medical practitioners employed by organisations conducting testing or within their practice. Tests cannot be supplied for use by pharmacists or other healthcare professionals outside the above settings. Furthermore, the TGA prohibits use of rapid antigen tests for use by individuals in their homes (self-testing).[33]

The basis for the existing restrictions on supply is because the correct interpretation of results is critical to support the public health response and this requires the involvement of a suitably qualified healthcare professional. The TGA specifies that rapid antigen point of care and serology based testing for COVID-19 should be conducted in conjunction with a medical practitioner who can provide an individual with appropriate advice and treatment. Additionally, staff need to be trained in appropriate specimen collection and infection management procedures.[32]

It should be noted that point of care rapid antigen tests are also subject to State-based restrictions on supply. Western Australia prohibits any supply of these tests.[34] South Australia and Queensland restrict supply to effectively State-based pathology services or State Health

[31] CDNA, April 2021. Australian National Disease Surveillance Plan for COVID-19. Pages 7 and 13 and Finkel report page 46.
[32] Conditions on all COVID-19 tests approved for ARTG inclusion, https://www.tga.gov.au/applying-tga-assessment-covid-19-test-inclusion-artg#conditions (accessed 5 July 2021).
[33] Warning to consumers and advertisers about COVID-19 test kits, https://www.tga.gov.au/media-release/warning-consumers-and-advertisers-about-covid-19-test-kits (accessed 5 July 2021).
[34] Prohibition on the use of Rapid Antigen Testing, https://www.wa.gov.au/government/publications/prohibition-the-use-of-rapid-antigen-testing (accessed 5 July 2021).

Departments.[35,36] Queensland does also allow supply to pathology services not affiliated with Pathology Queensland.[36]

5. Test performance – sensitivity, specificity, prevalence and predictive value

Before discussing the value proposition of rapid antigen tests in more detail and the use cases, it is important to understand the different terminology related to test performance. This is outlined below.

Sensitivity and specificity

The sensitivity of a test for an infectious disease identifies the capacity of the test to correctly identify individuals who are infected (true positives). The specificity of the test identifies the capacity of the test to correctly identify uninfected individuals (true negatives). Interpretation of these results using Roche's laboratory RT-PCR and rapid antigen performance metrics are outlined below.

Table 1: Interpreting sensitivity and specificity results using Roche's laboratory RT-PCR and rapid antigen test performance[37,38]

Sensitivity	**What does this mean?**
100% (lab based RT-PCR)	100% true positives 0% false negatives In other words – every infected individual was detected and no infected individuals were missed.
95.5% (rapid antigen)	95.5% true positives 4.5% false negatives In other words, the same test detected 95.5% of individuals who *were* infected and 4.5% of infected individuals were incorrectly reported as negative.
Specificity	**What does this mean?**
95.5% (Lab-based RT-PCR)	95.5% true negatives 4.5% false positives In other words – 95.5% of individuals who were not infected were accurately identified and 4.5% of uninfected individuals were identified as positive.
99.2% (rapid antigen)	99.2% true negatives 0.8% false positives In other words, the test accurately detected 99.2% of individuals who *were not* infected and 0.8% of uninfected individuals were incorrectly reported as a positive.

[35] Government of South Australia, https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs+and+practice+guidelines/infectious+disease+control/coronavirus+disease+2019+information+for+health+professionals/novel+coronavirus+%282019-ncov%29+infection+information+for+health+professionals (accessed 5 July 2021).

[36] Queensland Government, https://www.qld.gov.au/health/conditions/health-alerts/coronavirus-covid-19/stay-informed/testing-and-fever-clinics (accessed 5 July 2021).

[37] Roche SARS-CoV-2 Rapid Antigen Test Australian Instructions For Use 9901-NCOV-01G.

[38] Roche cobas SARS-CoV-2 6800/8800 Instructions For Use 09179917001-07EN.

In general, rapid antigen tests have lower sensitivity than RT-PCR tests and some have comparable specificity to RT-PCR. This means that RT-PCR tests return less false negatives than rapid antigen tests and similar false positives.

As mentioned above, TGA listed rapid antigen tests meet the Essential Principles outlined in TGA legislation and have a relatively high sensitivity and very high specificity, with performance parameters exceeding the thresholds set by the WHO and the European Centre for Disease Prevention and Control (ECDC) of sensitivity of 80% or over and specificity of 97% or over.[39,40]

Predictive value
The sensitivity and specificity of a test does not change with the prevalence of infection (i.e. the proportion of the population infected at a given time). However, the likelihood of obtaining a false positive or negative is influenced by prevalence because prevalence indicates the likelihood of a person being infected (pre-test probability). The impact of pre-test probability on test results is outlined in the Table 2 below.

Table 2: Impact of pre-test probability on test results (Source: United States Center for Disease Control)

Pre-test Probability*	Negative Predictive Value** (NPV)	Positive Predictive Value**(PPV)	Impact on Test Results
Low	High	Low	Increased likelihood of False Positives Increased likelihood of True Negatives
High	Low	High	Increased likelihood of True Positives Increased likelihood of False Negatives

*Sensitivity and specificity of tests are not affected by the pre-test probability
**Predictive values are affected by the pre-test probability

As can be seen from Table 2, tests typically perform best for excluding an infection when the pre-test probability is low. This means that in a country like Australia where the prevalence is low, when a sample returns a negative result, there is a high probability the result is accurate. Conversely, if a positive result is returned, there is a high probability the result is a false positive and confirmatory testing by RT-PCR is required.

A table outlining the positive and negative predictive value of the same test in different countries is outlined below. The sensitivity and specificity used in the table are that of Roche Diagnostics SARS-CoV-2 Rapid Antigen Test.

[39] Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays, Sept 2020.
[40] Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK, Nov 2020. Page 5.

Table 3: Impact of prevalence on predictive values in different countries

Country	Prevalence (as of 29/06/21)	Sensitivity	Specificity	PPV	NPV
Australia	0.001%	95.5%	99.2%	0.11%	100%
Singapore	0.005%	95.5%	99.2%	0.59%	99.99%
Spain	0.256%	95.5%	99.2%	23.45%	99.99%

Applying all the above concepts to the Australian setting (where we have a prevalence of 0.001%) to a test with the specificity and sensitivity values outlined in Table 3:

- **The test accurately detects 99.2% of individuals who *are not* infected and you can have very high confidence in these results.***
- **The same test will detect 95.5% of individuals who *are* infected but it is likely that positive results are false and confirmation of these results by RT-PCR is required.**

*Please note that all SARS-CoV-2 detection assays, including RT-PCR, are susceptible to sampling errors with the swab collection, which can impact results.

False negatives (missed cases) have been highlighted as a considerable concern in Australia, however as indicated in Table 4 below, using a test which has the same performance as the Roche SARS-CoV-2 Rapid Antigen Test produces very few false negatives in very low prevalence settings. In the Australian context, where the prevalence rate is 0.001 %, out of 10 million tests, 100 people will be expected to be infected. If the test has a sensitivity of 95.5%, then of those 100 infected people, 95 will be correctly identified cases (true positives) and only 5 individuals out of 10 million will be missed cases (false negative).

Table 4. Table with number of positive and negative results in example low prevalence population using sensitivity and specificity of Roche SARS-CoV-2 rapid antigen test

Prevalence	Population	Number of infected people	True positive	False negative	Number of non-infected people	True negative	False positive
0.001%	100,000	1	0.95	0.05	99,999	99,199	800
0.001%	1,000,000	10	9.5	0.5	999,990	991,990	8,000
0.001%	10 million	100	95	5	9,999,900	9,919,900	80,000

6. Value proposition of rapid antigen tests

With their extremely high sensitivity, laboratory RT-PCR tests remain the gold standard for diagnosing SARS-CoV-2. Rapid antigen tests have a lower sensitivity than RT-PCR but despite this, a study found that the quick turnaround time (minutes compared to days), ability to test

anywhere and the ability to potentially differentiate patients that are either infectious or those that are less/not infectious,[41] makes them a highly valued tool in controlling the pandemic.

In the Australian context, Roche believes that the value of rapid antigen tests lies in the following three attributes which make them a useful complement to laboratory RT-PCR testing in Australia.

a) Their very high specificity
b) The speed of obtaining results
c) The ease of use

a) Very high specificity

In a low prevalence setting like Australia where the number of infections in the community is low, the predictive value of high specificity of rapid antigen tests to exclude infection is enhanced which makes them ideal for identifying individuals who are NOT infected.

The benefits of identifying uninfected individuals is particularly useful in:

- Screening to reduce the risk of introducing or exporting the virus into and from certain settings, particularly high-risk settings to better protect vulnerable individuals and communities and workplaces and the community at large
- Screening to support a return to normal activities such as travelling and attending large entertainment and sporting events

Such use can protect the health of individuals whilst protecting the ability of businesses to continue to operate, supporting economic recovery and a return to normal life.

b) Speed of obtaining results

In addition to the value associated with rapidly identifying individuals that are NOT infected, rapid identification of individuals that ARE infected, particularly during an outbreak is also valuable.

Faster testing can:

- Enable the rapid triaging and management of potentially positive individuals by separating them from individuals that have tested negative, thereby reducing transmission and restrictions on movement of uninfected individuals, which is critical in situations like international arrivals and aged care facilities
- Facilitate faster public health responses as more transmissible variants of the virus evolve reducing the need for lockdowns
- Support testing compliance as individuals receive the results immediately and can isolate only if they are found to be infected and require confirmatory tests
- Reduce the time individuals who cannot work from home need to take off from work as they await testing results

It is widely recognised that the rapid availability of results and the capacity to take action are critical to managing COVID-19 and reducing transmission. Mathematical modelling has demonstrated that fast turnaround time is more important than test sensitivity in reducing cases.[42]

[41] Kruttgen et al., 2021. Comparison of the SARS-CoV-2 Rapid antigen test to the real star SARS-CoV-2 RT PCR kit. Journal of Virological Methods.
[42] Larremore et al., 2021. Test sensitivity is secondary to frequency and turnaround time for COVID-19 screening. Science Advances.

Given the emergence of highly transmissible strains of SARS-CoV-2, the speed of obtaining results is becoming even more critical, making the need for rapid tests even greater than before.

Additionally, the criticality of rapid testing was outlined in the Finkel Review into contact tracing which advised that rapid turnaround from specimen collection to notification of test result is critical to ensure efficiency of contact tracing and ensure downstream transmission risk is mitigated as quickly as possible.[36]

In May 2021, Singapore, which also has a relatively low prevalence of infections, approved the use of rapid antigen testing in symptomatic individuals on the basis that the quicker turnaround time for these tests compared to a PCR test, which resulted in faster public health actions for persons who test positive by rapid antigen tests.[43] Authorities concluded that the benefits of a rapid public health response outweighed the risks associated with lower performance of the tests. Prior to this announcement, in October 2020 Singapore had piloted the use of rapid antigen tests for its large migrant workforce – in addition to RT-PCR testing every 14 days. The government recognised that use of rapid antigen testing could result in fewer close contacts that will need to be quarantined, thereby minimising work disruptions for workers and employers.[44] Singapore also piloted the use of rapid antigen testing in events – the first one was in October 2020 at a sporting event with 250 attendees.[45]

The Finkel review also noted that notification of negative results within 24 hours is likely to increase testing compliance across a population.[46] The latter coincides with Higginson et al., 2020[7] who reported that Victoria's long delays in processing tests (5-7 days) may have caused public disobedience of self-isolation requirements while people waited for results. Given the level of COVID-fatigue in the community, Roche believes the speed of results will become even more important to ensure ongoing compliance.

- ***Ease of use***

Rapid antigen tests are easy to use, do not rely on the capacity of individuals to operate specialised equipment and are portable. Rapid antigen tests can be performed by healthcare professionals with a more rapid return of results than RT-PCR. They can also be performed almost anywhere, including in the home by untrained individuals (noting that self-testing is prohibited in Australia by the TGA).

The benefits of ease of use include:

- Increased capacity to be deployed as part of a mobile response effort to 'closed' environments such as mining sites, oil rigs, residential aged care facilities etc.
- Increased compliance with testing requirements for symptomatic individuals or those at higher risk of workplace exposure due to greater convenience for individuals
- A sustainable way to help transition from a pandemic to an endemic environment

The portability of rapid tests into closed environments can help keep workplaces functional during outbreaks. For example, the NSW Parliament adopted the use of rapid testing technologies

[43] Ministry of Health Singapore, https://www.moh.gov.sg/covid-19/selftestart (accessed 5 July 2021).
[44] The Strait Times Singapore, https://www.straitstimes.com/singapore/health/antigen-rapid-tests-piloted-for-quicker-detection-of-covid-19-infection-among (accessed 5 July 2021).
[45] The Strait Times Singapore, https://www.straitstimes.com/sport/combat-sports/mma-up-to-250-fans-allowed-for-oct-30-one-championship-fight-in-singapore (accessed 5 July 2021).
[46] Australian Government. National Contact Tracing Review, Nov 2020. Alan Finkel et al. Page 52.

(in this instance rapid RT-PCR) during a recent outbreak to continue performing vital Government functions.[47]

Roche believes that testing convenience is likely to have a significant impact on compliance with future testing requirements given the growing level of COVID fatigue in the community. A lack of testing can diminish the value of surveillance efforts which require reporting of various testing-related data to inform public health responses.

Improving the convenience of testing over current arrangements which require individuals with symptoms or are suspected of exposure to the virus to take time off work to line up at testing clinics (which may experience long queues during outbreaks) or visit their GP and then self-isolate until their results are returned may help in testing compliance.

While testing clinics offer RT-PCR tests for free, individuals who are tested by a GP need to pay a consultation fee unless the GP bulk bills. Therefore, allowing rapid antigen self-testing at home for ~$10 per test may be an attractive proposition for individuals for whom attending a clinic is inconvenient and attending a GP may be expensive.

7. International use cases for rapid tests

There are a number of countries and private entities that are either trialling or have successfully implemented rapid antigen tests as part of their testing regime. Many of the uses overseas leverage the key attributes of specificity, speed and ease of use.

A recent study based on the German experiences found that during the period where vaccination rates rose from 5% to 40%, rapid antigen testing had the largest effect on reducing infection numbers - this may be due to quicker and more effective contact tracing. The authors concluded rapid antigen testing could replace non-pharmaceutical interventions (NPIs), such as lockdowns which have high individual, societal, and economic costs and should remain as part of the strategy to contain SARS-CoV-2.[48]

Germany's initial response to the pandemic relied on NPIs but in time, as vaccination was rolled out, they replaced regular PCR tests for staff in many medical and nursing facilities. These had to be administered by medical doctors or in pharmacies. Self-tests were then approved by authorities for use in the home, rapid test centres were opened and one test per person per week was made available free of charge. The initial reliance on NPIs, accompanied by vaccines and a growing acceptance of the use of rapid tests is characteristic of developments in many countries.[49]

Other examples of acceptance of rapid antigen tests include:

- England - Residents will be provided with two rapid antigen tests per week. Individuals with a positive result will be expected to self-isolate and a confirmatory RT-PCR performed. If the RT-PCR test is negative, the individual can then resume as per normal.[50]

[47] Sydney Morning Herald, https://www.smh.com.au/politics/nsw/the-24-hours-that-plunged-nsw-parliament-into-covid-chaos-20210624-p58436.html (accessed 5 July 2021).
[48] Gabler et al., June 2021. The Effectiveness of Strategies to Contain SARS-CoV-2: Testing, Vaccinations and Non-pharmaceutical interventions. ECONtribute. Discussion Paper No. 100 - page 9 and abstract.
[49] Gabler et al., June 2021. The Effectiveness of Strategies to Contain SARS-CoV-2: Testing, Vaccinations and Non-pharmaceutical interventions. ECONtribute. Discussion Paper No. 100 - page 5.
[50] NHS Regular rapid lateral flow coronavirus (COVID-19) tests, https://www.nhs.uk/conditions/coronavirus-covid-19/testing/regular-rapid-coronavirus-tests-if-you-do-not-have-symptoms/ (accessed 5 July 2021).

- Singapore - The government has approved self-testing rapid antigen kits to be sold at pharmacies.[51]
- Canada - the government is supplying free rapid antigen tests for workplace screening of staff in critical sectors. The intention of the initiative is to add an additional layer of protection to these workers, not to replace any existing public health measures.[52]
- The Radisson Hotel Group offers rapid antigen testing (along with RT-PCR testing options) to guests for meetings and events across Europe, the Middle East and Africa[53]

8. Potential Australian use cases

Potential use cases based on leveraging the specificity, speed and ease of use of rapid tests are outlined below.

a) Testing to avoid introducing or exporting the virus into and from high-risk settings to protect health, avoid lockdowns and support economic recovery

Testing to exclude infection and therefore the introduction of the virus by visitors or workers into a high-risk setting would be an effective way to protect vulnerable communities, workplaces or individuals from an outbreak which could require an escalated public health response with the consequent individual and economic impacts of such a response.

High-risk settings include those where:

- individuals are at higher risk of contact with the virus due to workplace or other exposure or who can spread the virus further geographically if they are exposed (workers or travellers in quarantine, airline workers, hospital workers, workers in food processing, distribution and cold storage facilities)
- communities where individuals live in close proximity and therefore rapid transmission of the virus is possible (correctional or detention facilities, mining sites, oil rigs, homeless shelters and residential / crisis hostels, crowded or high density housing)
- communities with a high proportion of individuals at high-risk of a negative outcome from infection with the virus (Indigenous communities, aged care and disability residential facilities)

In fact, the CDC recommends high frequency testing to screen workers in high-risk and essential settings.[54] Furthermore, it notes that antigen tests have been used for screening in high-risk congregate housing settings, such as nursing homes, in which repeat testing has quickly identified people with COVID-19, informing infection prevention and control measures, thus preventing transmission. In this case, and where rapid test turnaround time is critical, there is value in providing immediate results with antigen tests, even though they may have lower sensitivity than nucleic acid tests (such as RT-PCR).

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[51] Health Sciences Authority Singapore, https://www.hsa.gov.sg/consumer-safety/articles/covid19_ARTselftests (accessed 5 July 2021).
[52] Government of Canada, https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/testing-screening-contact-tracing/workplace.html (accessed 5 July 2021).
[53] Radisson Hotel, https://www.hotelmanagement.net/operate/radisson-rolls-out-rapid-testing-service-for-emea-meetings (accessed 5 July 2021).
[54] CDC Interim Guidance for Antigen Testing for SARS-CoV-2, https://www.google.com/url?q=https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html&sa=D&source=editors&ust=1626152686172000&usg=AOvVaw0uRRajG34U8hI8vMWo-MQH (accessed 5 July 2021).

b) *Testing at large sporting / entertainment events to assist a return to normal and support sectoral economic recovery*

Rapid antigen tests can be conducted in individuals prior to attending a live event to ensure only individuals who test negative to the virus are granted access to the venue and minimise the risk of the event becoming a "super-spreader" event. Such testing could contribute to the recovery of the live entertainment industry (including live performance, venue based live music, major event and major professional sports) which have been impacted so significantly by the pandemic.

The live entertainment industry contributed approximately $36.5bn to the Australian economy in 2019 but, due to SARS-CoV-2 restrictions in 2020, this is expected to fall by 64% to $12.8bn.[55] Despite the easing of restrictions in 2021, the impact of the pandemic on the entertainment industry still continues with small outbreaks resulting in large events being postponed/cancelled when cases arise in the city/state in which the event is held (for example - Bluesfest 2021 was postponed due to one case in Byron Bay).

Other countries have adopted a different approach to enable live events to continue by utilising different testing regimes. For the UEFA Euro 2020 football games (now held in 2021), Germany has adopted an approach where spectators will be required to prove a negative RT-PCR or antigen result (via an app). Even though the stadium will only be 20% full, the events are still able to continue.[56] The Tokyo Olympics will adopt an approach where athletes and team officials are required to have tests every day by using a rapid antigen test as a first screen and in case of an unclear or positive test, the test is followed by a second screen using RT-PCR.[57]

As part of a research project, Spanish authorities in Barcelona allowed 5000 participants to enter into a large music event, provided the participants returned a negative rapid antigen test prior to entry. No large outbreaks occurred after the event, with only six people testing positive 15 days after the event. Researchers concluded it was highly unlikely that the six people who did test positive contracted the virus during the event.[58]

c) *Testing international and domestic travellers to re-open borders and support sectoral economic recovery*

A potential use for rapid tests (both RT-PCR and antigen) could be for international and domestic borders. Rapid testing for airline passengers prior to departure could be used in a domestic setting. In instances where passengers test positive on a rapid antigen test, results can be confirmed by point of care RT-PCR on location. This would help reduce the risk of transmission on the flight such as occurred recently on several domestic flights. It will also increase passenger confidence that they will not contract an infection on the flight or be inconvenienced by being required to isolate if an infected passenger or crew member was on board.

Similarly, individuals on a cruise can be tested prior to boarding and during the cruise to minimise the risk of infection and restore passenger confidence in sea travel.

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[55] Ernst and Young. The economic contribution of Australia's Live Entertainment Industry. Page 5.

[56] ISPO, https://www.ispo.com/en/know-how/uefa-euro-2020-and-corona-these-rules-apply-fans (accessed 5 July 2021).

[57] The Playbook Athletes and Officials, Tokyo 2020, April 2021, Version 2.

[58] Deutsche Welle, https://www.dw.com/en/coronavirus-no-big-outbreaks-after-barcelona-test-concert/a-57353466 (accessed 5 July 2021).

Increased confidence would help support the economic recovery of these industries but also co-dependent industries such as the tourism and hospitality sectors which have also been adversely impacted.

Another potential use is to test individuals as they cross domestic borders which can be closed to travellers to assist in the management of infection outbreaks.

d) Testing to allow more flexible risk-based quarantine arrangements and support sectoral and national economic recovery

Currently Australian international borders are closed (except for a travel bubble with New Zealand) and travel exemptions are required to travel in and out of Australia, with returning travellers needing to quarantine. Furthermore, many industries are not able to secure the necessary travel exemption required to secure visas to bring in employees from overseas to fill critical positions.

Rapid antigen testing may help strengthen Australia's quarantine arrangements whilst also allowing for a more risk-based and flexible approach. This may assist in restoring the tertiary education sector and address existing workforce shortages to enable Australian businesses to operate and contribute to the economy at full capacity again.

The Halton Report provided to the National Cabinet on Australia's quarantine arrangements noted that while quarantine offers Australia a first line of defence against the virus, no quarantine arrangements will ever be 100% risk-free and therefore testing and contact tracing, our secondary lines of defence, would remain critical. The report also recommended that more risk-based approaches to quarantine should be considered going forward.[59] Consideration of more risk-based approaches to quarantine form part of the Plan.

In Roche's view, rapid tests can assist to not only strengthen quarantine arrangements but also allow a risk-based approach and flexible quarantine arrangements for travellers who have spent a significant period of time in a low prevalence country. This may allow more students, workers and returning residents into Australia whilst continuing to protect the community.

For example, existing quarantine arrangements may be strengthened if rapid antigen testing of travellers exiting quarantine on their final day and also for a few days after was undertaken. Currently, laboratory-based RT-PCR testing is conducted during and a few days prior to the end of the quarantine period. This means that individuals can become infected after the final RT-PCR test is taken as they remain in the high-risk environment of quarantine, leading to testing positive after leaving quarantine (despite negative tests throughout), as has occurred recently in Australia and caused significant lockdowns. Rapid antigen testing on the last day of quarantine will increase the chances that only a person who is not infected leaves quarantine. Any positive tests could be confirmed through point of care RT-PCR which will provide results in under an hour. This will reduce the residual risk of an infected individual entering the community whilst avoiding unnecessary delays in exiting quarantine.

[59] Halton, 2020. National Review of Hotel Quarantine. Pages 3 and 18.

Whilst some sites have implemented RT-PCR testing on Day 16 as an additional safety measure[60], which is after the individuals have left quarantine and an individual is already in the community, the addition of rapid antigen testing at end of quarantine is still valuable.

Additionally, rapid antigen tests may also assist in reducing quarantine periods for travellers from other low prevalence countries as they are less likely to be infected with the virus or who have been vaccinated. This can increase the acceptability of Australia's quarantine arrangements and reduce costs for those paying for quarantine. For example, such individuals could be tested prior to boarding in-bound flights to reduce the risk of transmission on the flight, quarantine for seven days in a facility and then finish their quarantine period at home as has recently been suggested in the Plan. Suitable testing regimens which include rapid testing, could be implemented to ensure people are SARS-CoV-2 negative at the end of their quarantine period at home and individuals could be supported through a telehealth consultation during testing.

Reducing the cost of quarantine and allowing quarantine at home in low-risk situations may reduce the barriers to international students returning to study in Australia, particularly those who return to their country of origin on multiple occasions during the year.

9. Barriers to realising the full value of rapid antigen tests in Australia

Despite growing recognition that rapid antigen tests have a role in managing the pandemic and the Finkel Review recommending in November 2020 that a framework for the use of rapid antigen tests be established to support the public health response,[61] the Testing Framework in Australia has not been amended to endorse the use of these tests beyond use in outbreaks. This is leading to hesitancy in using these tests despite the clear value they represent.

TGA restrictions on supply and the prohibition of self-testing represent additional barriers to broader use.

While this cautious approach is understandable given our successes in suppressing the virus, it is unlikely to be a sustainable approach in the future as we move to COVID-Normal and will place Australia further out of step with comparable international jurisdictions if retained. Furthermore, it does not allow for the full potential value of the tests to be realised.

Public health authority concerns:
As noted above, public health authorities are reluctant to recommend the use of rapid tests despite the recognised potential value. Australian States and Territories have not adopted rapid antigen tests as part of their diagnostic protocol, and the PHLN, together with the CDNA have noted that while there may be benefits to rapid antigen tests, their use is not recommended due to some concerns.[62] Similarly, NSW Health has a position statement outlining the benefits and potential uses but does not recommend widespread use of rapid antigen tests.[63]

In terms of benefits, NSW Health states that the value of a sensitive rapid antigen assay (with high specificity) could be in the following scenarios:[61]

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[60] NSW Government, May 2021. Passengers leaving hotels who have completed 14 days mandatory quarantine. Page 1.
[61] Australian Government. Department of Health. National Contact Tracing Review - A report for the National Cabinet. Nov 2020. Author: Alan Finkel. Page 15.
[62] Public Health Laboratory Network – Communicable Diseases Network Australia Joint Statement on SARS-CoV-2 Rapid Antigen Tests, Oct 2020.
[63]NSW Health, Oct 2020. Role of COVID-19 Antigen Testing – NSW Health Pathology Discussion Paper.

- For screening in high-risk settings
- When community prevalence is high (such as during an outbreak)
- When testing someone with or without symptoms and within a reasonable timeframe of exposure to a newly confirmed case
- As part of 'mobile' response teams to 'closed' environments / remote locations
- When determining persistence of infectivity following nucleic acid testing positive case e.g for release from quarantine

It should be noted that many of these uses align with the use cases outlined earlier in this document.

It appears that much of the reluctance by public health authorities around the use of these tests appears to be around the sensitivity of the tests (i.e. identifying who is infected) and the low-prevalence of infection in Australia and the variability of tests on the market.

Roche's response to address the key concerns raised by public health authorities is outlined below.

a) *Rapid antigen tests are generally less sensitive and may be less specific compared to RT-PCR*

It should be noted that while there are limitations to the rapid tests, all diagnostic tests have limitations - even RT-PCR has limitations and can deliver false positive and negative results.

From Roche's portfolio, our rapid antigen tests have lower sensitivity but higher specificity than some of our laboratory-based RT-PCR tests. Information from Pathology Technology Australia (PTA) indicates that specificity in the rapid antigen tests registered for use in Australia, specificity is over 99%.

In relation to sensitivity, as noted earlier, mathematical modelling has demonstrated that fast turnaround time is more important than test sensitivity in reducing cases.[38] Furthermore, the slightly lower sensitivity of rapid antigen tests can be partially mitigated by repeat rapid antigen testing every 2-3 days with confirmatory testing by RT-PCR for positive samples, particularly in low prevalence settings.[64] As more rapid antigen tests are validated for use with sample types that are more convenient and less invasive to obtain, such as saliva or nasal swabs, the acceptability of conducting more frequent testing will be improved.

The Irish Health Information and Quality Authority examined various models of serial testing using rapid antigen tests in meat processing plants in combination with RT-PCR confirmation of positive results. The modelling demonstrated that compared to RT-PCR, serial rapid antigen testing may detect more true positive cases, reduce the number of false positives and decrease the cost of testing. However, results varied in models where rapid antigen testing was used more often and could result in the reverse effects of increasing days in self-isolation and increasing staff requirements, hence highlighting the importance of using appropriate testing protocols.[65]

[64] European Centre for Disease Prevention and Control, Nov 2020. Options for the use of rapid antigen tests for COVID-19 in the EU/EEA and the UK.

[65] Health Information and Quality Authority, 2021. Potential impact of different serial testing scenarios using rapid antigen detection tests (RADTs) to detect SARSCoV-2 in meat processing plant workers.

b) Variability in commercial rapid antigen tests

Roche recognises that not all rapid antigen tests for SARS-CoV-2 are equal and may have variable performance. However, all rapid tests registered for use in Australia by the TGA (including Roche's test) must meet the Australian essential principles for safety and performance of Therapeutic Goods (Medical Devices) Regulations 2002 . Concerns over variability can be addressed by the TGA publishing expanded test performance data on their website and procurement processes including performance thresholds acceptable to the purchaser. In addition, concern has been raised on the performance of tests with emerging variants. Many companies (including Roche) continuously monitor for new SARS-CoV-2 variants or mutations to ensure they are detected in both existing and new assays (be they rapid antigen tests or other test types).

c) Current testing using RT-PCR is accessible and widely available

It is important that Australia has a wide range of tests available to manage outbreaks. Outbreaks of COVID-19 can emerge and spread quickly, as evidenced by the rapid emergence of a 'second wave' in Melbourne between July and September 2020. Similarly, more infectious strains of the virus are emerging. For example, the current Delta strain is capable of infecting more individuals with much shorter exposure times, meaning rapid turnaround times for results are even more critical. Scalable rapid antigen testing is valuable to build up response capacity, particularly in low prevalence settings.[66]

In addition, a recent study concluded that RT-PCR testing alone should not determine clinical and public health policy, and the need for more accurate, frequent, and less invasive testing exists.[67]

Furthermore, there may be shortages of reagents or tests, or laboratory capacity to conduct RT-PCR tests may be overwhelmed in large outbreaks. The Finkel Review outlines the need to ensure adequate supplies of testing reagents and build stockpiles during quiet times and that pathology laboratories should use diagnostic instruments from multiple vendors to ensure resilience during times of global shortages of reagents.[68] Roche believes that to build national resilience, it is important to ensure there is a wide array of tests – laboratory based and point of care based such as rapid RT-PCR and antigen tests – available in the National Medicines Stockpile.

d) Point-of-care RT-PCR is available in many settings where users require a rapid turnaround time

Rapid point of care RT-PCR testing is available outside laboratories. However, and not dissimilar to the laboratory-based RT-PCR tests, these tests require a dedicated instrument (albeit small and portable), and trained personnel to use it. It is also limited by the number of samples it can run at one time and are more expensive than rapid antigen tests. Rapid antigen tests could be used where resources for this type of equipment are not available or not affordable.

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[66] Muhi et al., 2020. Multi-site assessment of rapid point of care antigen testing for the diagnosis of SARS-CoV-2 infection in a low prevalence setting. A validation and implementation study. The Lancet.

[67] Zhang et al., 2021. Insight into the practical performance of RT-PCR testing for SARS-CoV-2 using serological data: a cohort study. The Lancet.

[68] Australian Government. Department of Health. National Contact Tracing Review – A report for National Cabinet. Nov 2020. Author: Alan Finkel. Page 14.

e) *In some cases, rapid antigen tests require specific skills and a quality framework for test performance, interpretation and record keeping*

In Australia, there are already provisions which underpin a quality framework given the TGA restricts the supply of rapid antigen tests to suitably qualified healthcare professionals to ensure that results are appropriately interpreted and avoid a detrimental impact on the public health response.

Roche agrees with the PTA that some workplaces have already rolled out effective on-site testing and have adopted good protocols which can be modified to suit most settings as part of the Quality Framework. The availability of digital solutions such as apps can be used to manage data reporting and recording requirements which can address the concerns over mandatory reporting requirements.

The public health consequences of having false negatives is unacceptable.
All tests (including RT-PCR) with a sensitivity below 100% result in false negatives (missed cases). As rapid antigen tests have marginally lower sensitivity than RT-PCR tests, they can generate more false negative results i.e. they miss slightly more infected individuals than RT-PCR does. However, for a test with a sensitivity of 95.5%, in a low prevalence setting like Australia (prevalence of approx. 0.001%), the number of infected individuals missed would only be five individuals out of 10 million tests. Moreover, testing sensitivity can be further increased by repeating rapid antigen tests every 2-3 days, which reduces the number of missed cases. In addition, tests with faster result times can also reduce viral transmission which is a key aim of testing.

However, the key value proposition of rapid antigen tests is to rapidly identify individuals who are NOT infected by screening them prior to entering or exiting a high-risk environment or large public gathering or screening individuals within high-risk environments. When used for this purpose, the performance measure of importance is the specificity of the test i.e. how well the test performs to identify who is NOT infected. Using a test with 99.2% specificity applied to Australia's prevalence rates, 80,000 out of 10 million tests will report as false positives. However, as individuals are not actually infected, the false positive result does not have any adverse consequences for public health. Furthermore, their result can and should be confirmed by RT-PCR which can be performed using a rapid or laboratory-based test.

Therefore, despite the number of false positives associated with rapid antigen tests, they offer a valuable tool for screening, providing an additional layer of protection to the community through testing a population that is currently being missed through RT-PCR testing alone (which is only focussed on diagnosing individuals who are likely to be infected) and false positive results confirmed by RT-PCR, which would be reported for surveillance purposes.

TGA concerns:
Currently, the TGA has imposed restrictions on the supply of rapid tests to minimise the risk of incorrect interpretation of results. These restrictions on supply are limiting the number of health professionals who can perform the test, but who may be required as the number of infections in the future increase as we move to a COVID-Normal environment. Just as with the vaccination roll out, there is scope for a broader role for pharmacists. For example, pharmacists or other healthcare professionals could conduct testing as part of visits to workplaces or aged care facilities and should not be excluded from being able to perform these services.

The TGA has prohibited self-testing for SARS-COV-2 presumably for similar reasons to their restrictions on supply and lack of result reporting which is required to support surveillance activities. It should be noted that, following a pilot, other countries such as Singapore are using self-testing with authorities recently approving various self-test rapid antigen tests to be sold at pharmacies (including from Roche Diagnostics).[69] Concerns about data loss could be managed through digital tools such as an App which can transmit test results where required.

A further possible concern may be around the capacity for individuals to collect a suitable sample, resulting in lower performance of the test compared to the test being performed by a trained healthcare professional. However, the same perception of lower performance was initially raised with HIV self-testing. This has shown to be unfounded[70] and HIV rapid tests have been available for self-testing in Australia since 2020.

A recent study of individuals with a high suspicion of COVID-19, examined rapid antigen testing of patients using self-collected nasal swabs and healthcare professional-collected nasopharyngeal swabs, both sampling techniques resulted in 91.4% sensitivity compared to RT-PCR, with 98.4% specificity for patient self-collected and 100% for professional-collected samples. Notably, 85.3% of participants reported that self-sampling was easy to perform.[71]

As Australia moves to an environment where the majority of the population is vaccinated and treatments become available, the TGA may need to re-assess the risk/benefit of continuing with the current prohibition on self-testing. As mentioned earlier, self-testing may be a way to encourage testing in an environment of COVID-fatigue where symptomatic individuals will forgo RT-PCR testing altogether and may reduce the value of surveillance activities. There may be a point at which any testing provided in the home is better than none and may prevent infected individuals from leaving home if positive. Being able to support continuity of testing will enable more data to be collected and improve the determination of appropriate public health responses.

10. Roche Diagnostics Australia's policy positions:

Based on the information in his document, there is a clear case and value for rapid tests to be included in the CDNA PHLN Testing Framework supported by guidelines on a quality framework that is suitable for the Australian context. These tests provide additional benefits to existing testing modalities and should be used to *complement* the gold standard - laboratory RT-PCR.

Furthermore, the TGA should consider expanding testing capability for rapid antigen tests to include pharmacists and other healthcare professionals and eventually allow patient self-testing. This would provide for enhanced and efficient access to the public for SARS-CoV-2 testing whilst also providing rapid test results.

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[69] https://www.hsa.gov.sg/consumer-safety/articles/covid19_ARTselftests (accessed 05 July 2021).

[70] Figueroa et al., 2018. Reliability of HIV rapid diagnostic tests for self-testing compared with testing by health-care workers: a systematic review and meta-analysis. The Lancet.

[71] Nikolai et al., 2021. Anterior nasal versus nasal mid-turbinate sampling for a SARS-CoV-2 antigen-detecting rapid test: does localisation or professional collection matter? MedRexiv. PREPRINT.

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The German step-wise approach to rolling out rapid antigen tests and potentially the use of pilots provides an indication of how Australia could transition from its currently conservative position on these tests.

However, more broadly than rapid antigen tests, we need to ensure we are prepared to manage surges in cases as we transition from suppressing the virus to managing the virus. Such preparedness would include regularly updating the Testing Framework provisions to:

- Anticipate future needs based on evolving epidemiological contexts and technical advancements
- Consider adapting testing recommendations to take into account risk, ongoing sustainability and impact on testing compliance

There is also value in diversifying the availability of testing technologies to manage outbreaks, which are likely to be a continuing feature of the foreseeable future until vaccination at a global level has been completed. This will ensure that we have sufficient system capacity to optimise our public health responses, irrespective of when and where the outbreak occurs.

Roche considers that the following key steps need to be undertaken as a priority to safely and successfully transition to COVID-Normal.

Policy positions:

1. The Testing Framework developed by the Public Health Laboratory Network (PHLN) and Communicable Diseases Network Australia (CDNA) be amended to support the use of rapid tests to:
    a. cover use in high-risk settings as outlined in this document
    b. strengthen quarantine arrangements
    c. support a more risk-based approach to quarantine
    d. screen domestic airline travellers
    e. screen prior to large public gatherings
2. The Testing Framework include guidelines on standards and elements for a quality framework to support the use of rapid tests.
3. The TGA extend the supply of antigen rapid tests to other health professionals such as pharmacists who can be trained to deliver such testing within a quality framework.
4. States / Territories which place restrictions on supply of rapid antigen tests additional to those imposed by the TGA align with TGA provisions.
5. Funding for testing beyond laboratory-based RT-PCR be made available for use in settings aligned to the quality framework outlined in Recommendation 2.
6. Where the high-risk setting is publicly funded, such as quarantine or residential aged care facilities, additional funding allocations be incorporated into the operating budget.
7. Where the high-risk setting is a private sector small - medium enterprise, grant funding or tax offsets be made available to conduct frequent workplace screening.
8. The TGA collaborates with the CDNA and PHLN to explore the conditions under which the prohibition on self-testing can be lifted to align with international counterparts.
9. Government conducts pilots to support the broader use of rapid antigen tests, including self-testing.
10. The National Medicines Stockpile ensures that a reasonable diversity of testing technologies as well as a diversity of suppliers of the same testing technology are available to enable a public health response at scale.

11. The evolving role of other emerging technologies, such as serology based testing (laboratory or point of care) be reviewed in anticipation of the vaccination targets being reached by the end of the year.