Testing Framework for COVID-19 in Australia

February 2021

Contents

1. Background

Australia continues to follow a suppression strategy in response to COVID-19. Our goal is to have no community transmission of SARS-CoV-2.[1] We accept that outbreaks will remain a risk. A key priority of the public health response is to rapidly detect all infections and identify their source. This ensures that there are no unrecognised chains of transmission in the community. Targeted testing is crucial to this response. As Australia moves closer to achieving our goal, we need a revised testing framework. Australia's approach needs to consider testing requirements in a low/zero prevalence society which enable early detection of cases, this in turn supports a rapid and successful outbreak response.

1.1 Strategic context

This document provides a national framework to guide local approaches to testing. Individual states and territories can apply this framework to fit their local circumstances.

This framework for COVID-19 testing in Australia replaces the previous version included as an appendix to the May 2020 version of the *Australian National Disease Surveillance Plan for COVID-19*[2] *('Surveillance Plan')*. It is consistent with the *COVID-19 Communicable Diseases Network Australia (CDNA) National Guidelines for Public Health Units*[3] *('National Guidelines')*. Additionally, it is supported by the *Surveillance Plan*, which includes the monitoring of testing rates among its key components. The *Public Health Laboratory Network (PHLN) Guidance on Laboratory Testing for SARS-CoV-2*[4] outlines testing and specimen collection approaches.

The management of COVID-19 outbreaks and associated testing in residential care settings, including for aged care and disability care, are specifically addressed in the *CDNA National Guidelines for the Prevention, Control and Public Health Management of COVID-19 Outbreaks in Residential Care Facilities in Australia.*[5] The *CDNA National Guidelines for remote Aboriginal and Torres Strait Islander communities for COVID-19* provide specific guidance for testing in remote communities.[6] The modelling work referred to in this guidance has more information about the potential impact of testing strategies in remote and regional settings.[7]

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[1] AHPPC Statement on 24 July 2020. AHPPC statement on strategic direction. https://www.health.gov.au/news/australian-health-protection-principal-committee-ahppc-statement-on-strategic-direction

[2] CDNA Australian National Disease Surveillance Plan for COVID-19 https://www.health.gov.au/resources/publications/australian-national-disease-surveillance-plan-for-covid-19.

[3] Coronavirus Disease 2019 (COVID-19) CDNA National guidelines for public health units. https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-novel-coronavirus.htm

[4] PHLN guidance on laboratory testing for SARS-CoV-2 (the virus that causes COVID-19). https://www.health.gov.au/resources/publications/phln-guidance-on-laboratory-testing-for-sars-cov-2-the-virus-that-causes-covid-19

[5] Coronavirus (COVID-19) guidelines for outbreaks in residential care facilities. https://www.health.gov.au/resources/publications/coronavirus-covid-19-guidelines-for-outbreaks-in-residential-care-facilities

[6] CDNA National Guidelines for remote Aboriginal and Torres Strait Islander communities for COVID-19. https://www.health.gov.au/resources/publications/cdna-national-guidance-for-remote-aboriginal-and-torres-strait-islander-communities-for-covid-19

[7] Impact of COVID-19 in remote and regional settings. https://www.health.gov.au/resources/publications/impact-of-covid-19-in-remote-and-regional-settings

Serosurveillance is the term used for testing to understand how many people have had past SARS-CoV-2 infection at the community level. This is outside the scope of this framework and is separately described in the *Surveillance Plan*.

2. Targeting of COVID-19 testing in Australia

Effective, efficient and equitable testing needs to target:

- the local epidemiology
- the community
- the public health and laboratory capacity.

The testing approach must be responsive to changes over time. Testing must also strike the right balance between maintaining epidemic control and protecting the sustainability of laboratory and testing site capacity. In order to be objective-driven and sustainable, this framework outlines approaches to testing in geographical zones categorised according to three differing epidemiological contexts, referred to as 'Epidemiological Zones'. Testing approaches for each Epidemiological Zone, outlined below, focus on:

- prioritising groups for testing based on greatest risk (Section 5)
- adopting relevant testing methodologies and technologies that best suit the epidemiological context (Section 6).

State and territory jurisdictions should consider the optimum distribution of testing within their own context, with reference to the identified priority groups.

As the pandemic evolves, new diagnostic testing technologies for SARS-CoV-2 are rapidly emerging in the domestic and international markets. This offers Australia the opportunity to investigate testing strategies that may be complementary to, although not a replacement for, gold standard laboratory-based methods.

PHLN has established the Working Group on Emerging SARS-CoV-2 Testing Technology. The working group will provide clear and consistent evidence-based strategic advice on the role and options for use of emerging testing technology in the Australian context. It will consider the technical and public health opportunities, and benefits and limitations of devices designed to diagnose SARS-CoV-2 infection within and outside the health sector. This will minimise inappropriate use of devices by non-health users. The working group will also provide strategic advice on the use of these emerging technologies to inform Australia's testing strategy for COVID-19. The working group includes representation from CDNA.

Annex A contains technical guidance on applying emerging SARS-CoV-2 testing technology in Australia. Decision makers should seek expert public health and laboratory advice prior to their use.

Section 7 outlines data collection requirements to understand the amount of testing being conducted. Section 8 describes the key enablers to testing.

3. Priority groups for testing

This framework identifies four priority groups for the targeted testing in Australia. The emphasis on particular priority groups differs across Epidemiological Zones to meet the objective of the public health response.

Priority Group 1. People with COVID-19 compatible symptoms

The main approach for identifying people with an active SARS-CoV-2 infection is to test people with COVID-19 compatible symptoms. The *National Guidelines* define these symptoms. The rationale is that people with symptoms consistent with COVID-19 have a higher probability of testing positive for SARS-CoV-2 than people without those symptoms. They may also present a higher risk of transmission to others. This group remains a priority across all Epidemiological Zones.

Priority Group 2. People with known recent exposure to SARS-CoV-2 (contacts)

Contacts of known COVID-19 cases are at greatest risk of infection. The *National Guidelines* recommend that close downstream contacts[8] of a case undergo quarantine for 14 days after the last close contact with the case during the case's infectious period (Day 0 of quarantine). Monitoring contacts for the development of symptoms that could be consistent with COVID-19 is essential, as is prompt referral for testing if symptoms develop (Priority Group 1).

The *National Guidelines* recommend testing close contacts even if they remain asymptomatic throughout the quarantine period. The timing of routine testing of asymptomatic contacts is typically on entry to and exit from quarantine but may be dependent on the epidemiological context.

Priority Group 3. People at higher risk of exposure to SARS-CoV-2

People who have frequent, close or extended contact with others have the potential for greater exposure to SARS-CoV-2. People at increased risk of exposure include those:

- with a travel history to areas with higher rates of COVID-19, through international or domestic travel,
- who care for people with COVID-19, or
- who have contact with people who are more likely to have an active infection.

Identification of these groups is predominantly through occupational groups and may include, but not limited to:

- international border staff
- workers supporting quarantine and isolation services
- air and maritime crew
- health care workers and aged care workers with direct patient contact.

[8] Downstream contacts are individuals who may become infected as a result of contact with a case during the infective period of the case.

Depending on the epidemiological context, casual and mobile workers who work across multiple settings (e.g. cleaners, rideshare service and taxi drivers, security personnel) may also be at increased risk of exposure. This might be because:

- they have multiple potential exposure points
- they may have a larger number of work colleagues (who may feel that they need to continue working despite being unwell)
- there may be challenges in health messaging.

Priority Group 4. *People in high- and special-risk settings, including where disease amplification is likely or where people live or visit who are at increased risk of severe disease and death.*

Settings where disease is likely to readily transmit and amplify if an infectious case is introduced are those:

- with a high population density,
- where people are living or working in close proximity to others, or
- with specific environmental conditions.

Older people are at the highest risk of severe COVID-19 outcomes. Other people with certain pre-existing conditions are also at increased risk of severe COVID-19. Information on those at high risk of severe disease is available on the Department of Health website.[9]

These settings may include, but are not limited to:

- health care settings
- residential aged care settings
- residential care settings
- crowded or high-density housing
- Aboriginal and Torres Strait Islander communities
- correctional and detention facilities
- homeless shelters and residential/ crisis hostels
- mining sites, and
- food processing, distribution and cold storage facilities, including abattoirs.

4. Asymptomatic testing and workplace surveillance

There have been reports of asymptomatic infections at the time of testing. However many of these cases develop some symptoms at a later stage of infection (i.e. they tested when pre-symptomatic). We do not fully understand the proportion of cases that are truly asymptomatic through the course of their infection.

CDNA, PHLN and AHPPC recommend regular asymptomatic testing targeted to staff working in COVID-19 quarantine and isolation settings who are at risk of exposure to COVID-19[10].

[9] Australian Government Department of Health. Advice for people at risk of coronavirus (COVID-19) https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/advice-for-people-at-risk-of-coronavirus-covid-19

[10] AHPPC Statement on 17 November 2020. AHPPC statement on COVID-19: Routine Testing of Hotel Quarantine Workers https://www.health.gov.au/news/australian-health-protection-principal-committee-ahppc-statement-on-covid-19-routine-testing-of-hotel-quarantine-workers

This is to support and to protect the wellbeing of quarantine workers and the wider community.

Currently, the CDNA, PHLN and the Australian Health Protection Principal Committee (AHPPC) do not support large-scale, non-targeted testing for SARS-CoV-2 in asymptomatic people as part of the public health response. Non-targeted asymptomatic testing is neither epidemiologically sound nor a cost-effective approach to identify disease transmission.[11,12] Mathematical modelling shows that testing of non-targeted asymptomatic individuals is not an efficient way to detect community transmission[13]. This testing framework outlines where asymptomatic testing is best targeted to inform the public health response (Section 5).

There is growing interest from various industries to introduce programs for COVID-19 testing of asymptomatic employees to support a return to work and/or as a business continuity measure (that rely on assumptions that may or may not be based on sound evidence). There are key principles and requirements that employers should consider before deciding to start a COVID-19 employee testing program outside of public health-led testing programs. A guideline is in development. A COVID-19 employee testing program can be a complement to, not a replacement for, comprehensive COVID-safe business continuity measures.

Targeted asymptomatic testing approaches, including employee testing programs, must be developed in consultation with relevant public health authorities and laboratory directors well in advance of implementation. This is to ensure:

- the use of the most appropriate and effective testing approaches;
- the establishment of processes for reporting positive and negative tests;
- understanding of requirements for obtaining and reporting confirmatory testing;
- the application of current public health guidance.

Widespread low priority testing may increase laboratory turnaround times (TATs) for high priority testing. Therefore, if there are laboratory capability and capacity constraints, suspending routine COVID-19 employee testing programs that collect specimens from asymptomatic individuals until these constraints have lifted is recommended.

5. Testing prioritisation by Epidemiological Zone

Broadly defined Epidemiological Zones provide guidance to jurisdictions on testing approaches to meet the relevant public health objective. There may be more than one Epidemiological Zone occurring at the same time within a jurisdiction. This requires different, localised approaches to testing. A summary of testing prioritisation is at Table 1, with each Epidemiological Zone addressed in more detail in the sections below.

[11]AHPPC Statement on 21 August 2020. Australian Health Protection Principal Committee (AHPPC) updated statement on the role of asymptomatic testing. https://www.health.gov.au/news/australian-health-protection-principal-committee-ahppc-updated-statement-on-the-role-of-asymptomatic-testing.

[12] PHLN statement on asymptomatic testing for SARS-CoV-2. https://www.health.gov.au/resources/publications/phln-statement-on-asymptomatic-testing-for-sars-cov-2.

[13] Lokuge K, Banks E, Davies S, Roberts L, Street T, O'Donovan D, Caleo G, Glass K. Exit strategies: optimising feasible surveillance for detection, elimination and ongoing prevention of COVID-19 community transmission. medRxiv doi: 10.1101/2020.04.19.20071217.

Table 1. Summary of testing prioritisation by Epidemiological Zone

Priority Group	Epidemiological Zone 1 No community transmission	Epidemiological Zone 2 Community transmission	Epidemiological Zone 3 Community transmission placing burden on response capacity
1. People with COVID-19 compatible symptoms	High priority. Particularly important to test patients presenting to hospital with pneumonia or acute respiratory infection	High priority. Particularly important to promote in areas where there may be concern for potentially undetected chains of transmission.	High priority. Particularly important to promote in areas where there may be concern for potentially undetected chains of transmission
2. People with known recent exposure to SARS-CoV-2 (asymptomatic)	High priority for those who have known recent exposure to SARS-CoV-2, including in inter-jurisdictional outbreaks and border communities.	Close contacts may be tested on entry and exit from quarantine. To support upstream contact tracing where source of infection is uncertain.	May be rationalised.
3. People at higher risk of exposure to SARS-CoV-2 (asymptomatic)	High priority for return travellers and for people working at the border or supporting quarantine programs.	As per Epidemiological Zone 1, with the addition of testing high-risk groups based on unexplained onset of atypical or non-specific symptoms.	As per Epidemiological Zone 2.
4. People in high- and special-risk settings, including where disease amplification is likely (asymptomatic)	Not recommended.	Testing around a single case or outbreak. Public health-led routine screening.	Testing is prioritised for people who have a higher risk of more severe disease outcomes. Any industry-led workplace screening should be put on hold.

5.1 Epidemiological Zone 1 – No community transmission

Epidemiological context No locally acquired cases outside of returned travellers in quarantine.

Testing focus

The objective in this Epidemiological Zone is to increase confidence that SARS-CoV-2 transmission is not continuing undetected and that rapid identification of any imported cases in the community occurs to initiate a move to 'outbreak response' as quickly as possible. Detecting 'zero' COVID-19 cases with confidence requires unfeasibly high levels of testing. Therefore testing in this Epidemiological Zone should focus on:

- Priority Group 1 - People with COVID-19 compatible symptoms
- Priority Group 3 - People at risk of exposure to SARS-CoV-2.

Encouraging people with COVID-19 compatible symptoms and with known recent exposure to SARS-CoV-2 to promptly present for testing continues to be important even in extremely low prevalence contexts. Testing should be encouraged regardless of symptom severity. In

this context, it is particularly important to test all individuals presenting to hospital with pneumonia or acute respiratory infection. Testing individuals with severe disease may mitigate the risk of introduction of the virus to a high-risk setting, should there be unknown community transmission. In geographical areas where wastewater testing detects the presence of SARS-CoV-2, it is important to further encourage symptomatic individuals in the community to present for testing.

In this Epidemiological Zone, screening of asymptomatic groups should focus on where the risk of virus introduction is greatest. In the absence of disease within the zone, the greatest risk is at the border. Placing returning international travellers in quarantine and testing on entry and exit, as well as prompt testing of any returned traveller who develops symptoms, minimises the risk of introduction. Further, regular screening should target groups with high levels of contact with people who have been overseas or to higher Epidemiological Zones. As borders open up and travel increases, asymptomatic screening is important to detect unrecognised cases early. In particular, regular, routine testing of workers in COVID-19 quarantine and isolation settings is recommended[10]. Workers who are at high risk of exposure should be tested at least every seven days.

The practice of placing returning domestic travellers, from areas with SARS-CoV-2 in circulation, into quarantine varies by jurisdiction. The decision to conduct asymptomatic testing in these quarantined individuals is at the discretion of the jurisdiction.

5.2 Epidemiological Zone 2 – Community transmission

Epidemiological context Sporadic cases and clusters, through to wide spread community transmission, with laboratory testing and public health capacity meeting testing demand.

Testing focus

The objective in this Epidemiological Zone is to identify active cases to reduce further spread of infection in the defined area. Testing in this context also informs understanding of the characteristics of infected individuals and what factors are driving transmission.

To reduce the spread of SARS-CoV-2 and control transmission within the community, everyone with COVID-19 compatible symptoms should be encouraged to present for testing as soon as possible after symptom onset (Priority Group 1). This is particularly important in areas with community transmission where there may be concern for potentially undetected chains of transmission.

Close contacts who remain asymptomatic throughout their quarantine period (Priority Group 2) are required to be tested. Testing in this group is particularly important if the primary close contact is associated with a high risk setting. Asymptomatic contacts may be tested upon entry to and (if appropriate) exit from quarantine. The *National Guidelines* provide further detail on timing of this testing.

Upstream contact tracing[14] of cases without an epidemiological link in their exposure period aims to identify the index case. This is important to identify and manage unrecognised chains of transmission. This includes testing people who are currently asymptomatic. Serology may be of value in this context.

[14] Upstream contacts are individuals who are potential sources of infection for a particular case, with contact within the incubation period of the case and the infective period of the contact.

Screening activities to minimise the risk at the border continues to be important in this epidemiological context.

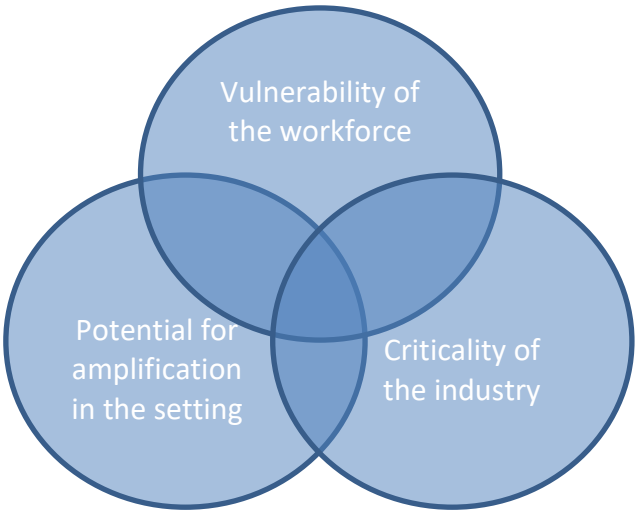
A high clinical suspicion and testing for COVID-19 of people at risk of exposure (Priority Group 3) who present with sudden and unexplained onset of atypical or non-specific symptoms is supported based on clinical and public health judgment. Atypical or non-specific symptoms may include fatigue, muscle pain, joint pain, diarrhoea, nausea/ vomiting and loss of appetite, without accompanying acute respiratory infection symptoms.

Testing of asymptomatic people should be considered for public health management in high and special-risk settings (Priority Group 4) where a single case or outbreak is identified. The aims are to:

- identify the source of introduction
- facilitate early detection of pre-symptomatic cases and mitigate further transmission
- minimise the overall duration of isolation/ quarantine experienced by people with ongoing close contact.

The *National Guidelines* outline a program of repeat testing in these settings, where a single case or outbreak is identified. This will identify those who are pre-symptomatic and ensure their absence from the setting (or appropriate isolation within the setting) until safe to return.

Public health-led, routine asymptomatic testing in high- and special-risk settings can be valuable in this epidemiological context. In addition to the potential for early detection of the virus in these settings, strategically selected industries or workplaces can act as a bridge to communities otherwise difficult to reach. Selection of workplaces or industries may be guided through consideration of the intersection of three elements:



Asymptomatic people tested as a part of screening at workplaces or borders are not required to stay home until a negative test result is returned, unless advised by a public health unit or relevant jurisdictional authorities.

5.3 Epidemiological Zone 3 – Community transmission placing burden on response capacity

Epidemiological context Wide spread community transmission, with testing demand exceeding laboratory and public health capacity.

Testing focus

The objective of this Epidemiological Zone is to identify active cases to reduce further spread of infection in the defined area, while preserving laboratory testing and public health capacity.

When disease is widespread, laboratory testing and public health capacity can become overwhelmed. In this situation the turnaround time (TAT) of a test is crucial. Rapid turnaround of tests from specimen collection to notification of test results (negative results and confirmed cases) is critical to ensure the efficiency and effectiveness of the contact tracing process.[15] Rapid notification of confirmed cases will ensure downstream transmission risk is mitigated as quickly as possible.

TATs are dependent on:

- the timeliness of specimen transportation from the collection site to the laboratory
- laboratory-specific resources
- the level of testing demand on any given day
- the needs of specific patient populations according to local priorities
- integration of technology
- result distribution method.

TATs increase when testing rates surge or need to be maintained at a high level over a long period of time. Prioritisation needs to occur at the stage of specimen collection, rather than at the laboratory. For this reason, close monitoring of TATs and clear and rapid communication to public health units and clinicians is key to a responsive testing strategy.

Encouraging people with COVID-19 compatible symptoms (Priority Group 1) to present as soon as possible after symptom onset continues to be important in this Epidemiological Zone.

Modelling has shown that testing symptomatic individuals, with concurrent isolation and subsequent contact tracing if possible, results in a steep decline in onward transmission of infection. However, the benefits of testing contacts (Priority Group 2) may be lost once capacity is exceeded and TATs increase. If TATs continue to increase, further rationalisation of testing should be considered, for example, limiting testing to close contacts who become symptomatic (Priority 1) while in quarantine.

Testing of people at risk of exposure and people in high and special-risk settings remains consistent with Epidemiological Zone 2. When constraints in laboratory capacity exist, testing of these groups may be further prioritised to people who have a higher risk of more severe disease outcomes.

[15] Commonwealth of Australia. National Contact Tracing Review. 13 November 2020. https://www.health.gov.au/resources/publications/national-contact-tracing-review

When constraints in laboratory capacity exist, asymptomatic testing not led by public health, e.g. asymptomatic COVID-19 employee testing programs, should be put on hold until these constraints have been relieved.

6. Testing technology and methodology by Epidemiological Zone

Testing technology	
Laboratory-based reverse transcription polymerase chain reaction (RT-PCR)	
Epidemiological Zone 1	Gold standard diagnostic test, critical for identifying current infection. In occupational and vulnerable population settings, consider using more acceptable collection methods (e.g. saliva), where these are validated, for easier administration and repeat testing and consider employing pooling strategies[16] when the prevalence or pretest probability is low. Pooling will assist conservation of RT-PCR testing consumables and laboratory capacity. These methodologies require laboratory validation. PHLN advice should be sought to determine current availability and utility.
Epidemiological Zone 2	Reserved for symptomatic testing, upstream contact tracing and testing close contacts (symptomatic and asymptomatic). As per Epidemiological Zone 1, consider using more acceptable collection methods, where validated. Pooling strategies may no longer be appropriate as prevalence or pretest probability rises. PHLN should be consulted to determine current availability and utility.
Epidemiological Zone 3	Reserved for symptomatic testing and upstream contact tracing when TATs exceed 24 hours at the 90th percentile. As per Epidemiological Zone 1, consider using more acceptable collection methods, where validated. Pooling strategy unlikely to be viable in this epidemiological context as prevalence or pretest probability likely to be too high. PHLN should be consulted to determine current availability and utility.
Point-of-care RT-PCR e.g. GeneXpert, BioFire FilmArray	
Epidemiological Zone 1	Use point-of-care RT-PCR systems in settings where access to laboratory-based testing is not available or a rapid turn-around-time (TAT) to result is required. This might be in rural and remote communities or hospital intensive care units. This enables early identification of current infection. These systems are low throughput and expensive.
Epidemiological Zone 2	As per Epidemiological Zone 1.
Epidemiological Zone 3	As per Epidemiological Zone 1.
Laboratory-based serology tests	

[16] Pooling involves combining several samples together in a batch or pooled sample, then testing the pooled sample. This approach increases the number of individuals that can be tested using the same amount of resources. Further information can be found at Annex A.

Testing technology	
Epidemiological Zone 1	Reserved for where the result will influence individual patient or outbreak management, such as: 1. Patients who have had symptoms consistent with COVID-19, but are RT-PCR negative or were not tested by RT-PCR during their acute illness; or have unexpected positive or inconclusive results on RT-PCR assays. 2. Upstream contacts of a case with uncertain epidemiological links. 3. To identify earlier undiagnosed cases (who might have had asymptomatic infection) in an affected household, workplace or outbreak setting, where this might influence quarantine decisions for individuals and outbreak management. Refer to PHLN advice[17] on serology testing to understand other appropriate contexts for use.
Epidemiological Zone 2	As per Epidemiological Zone 1
Epidemiological Zone 3	As per Epidemiological Zone 1 Limited utility in this context. Seek advice from laboratory for appropriate application.
Rapid antigen or rapid non-RT-PCR nucleic acid amplification tests (NAAT) (i.e. LAMP tests) at the point-of-care (or near point of care)	
Epidemiological Zone 1	Rapid antigen and rapid NAAT tests are not recommended for widespread use in low prevalence environments. May have utility in outbreak settings.
Epidemiological Zone 2	The analytical performance and possible uses for rapid antigen and rapid NAAT tests are being evaluated as a matter of urgency. There are many logistical and regulatory challenges to consider. Currently PHLN and CDNA recommend that rapid antigen and rapid NAAT tests are only used in specific contexts and settings for public health investigation purposes where the pre-test probability is high. For example in an outbreak setting or where community transmission is established. All presumptive positive cases must be confirmed using RT-PCR testing. The clinical utility of rapid antigen and rapid NAAT tests for screening asymptomatic population groups in low prevalence scenarios is still to be established. If used for public health investigation purposes, reflex RT-PCR of positive detections is required for confirmation. PHLN and CDNA also recommend reflex RT-PCR of suspected COVID-19 cases that return a negative rapid antigen test result. See Annex A for further information on the benefits and limitations of rapid antigen tests and rapid NAAT tests.

[17] PHLN. 3 September 2020. PHLN guidance on serological testing in COVID-19. https://www.health.gov.au/resources/publications/phln-guidance-for-serological-testing-in-covid-19

Testing technology	
Epidemiological Zone 3	As per Epidemiological Zone 2. The clinical utility of rapid antigen and rapid NAAT tests for screening asymptomatic population groups in high prevalence scenarios is still to be established. However in this epidemiological scenario, in addition to use for public health investigation purposes, this technology may prove useful as a screening test for individuals in high risk settings (i.e. high risk of exposure/transmission) where the pre-test probability is high. It offers rapid results in relevant settings, while reducing pressure on RT-PCR capacity. Positive detections would require RT-PCR for confirmation. PHLN and CDNA also recommend reflex RT-PCR of suspected COVID-19 cases that return a negative rapid antigen test result.
Genomic sequencing	
Epidemiological Zone 1	Genomics can differentiate between SARS-CoV-2 strains introduced from overseas or interstate and local transmission, and can assist in identifying a source or index case. Genomics is also important for monitoring virus evolution. In this epidemiological context, the intention should be to sequence every positive case.
Epidemiological Zone 2	May be used for new local outbreaks to identify links that cannot be confirmed epidemiologically. The intention in this epidemiological context should be to sequence every positive case, noting that prioritisation may be required depending on capacity.
Epidemiological Zone 3	Particularly important in cases with uncertain epidemiological links. Important to sequence widely to ensure the data repository is representative and the most value can be derived from analysis. If wide-scale transmission, sequencing will likely require prioritisation due to longer turn-around-time relative to RT-PCR.
Testing methodology	
Wastewater testing (RT-PCR or genomic sequencing)	
Epidemiological Zone 1	To detect the presence of SARS-CoV-2 in the community, as a way to indicate whether COVID-19 has truly been contained in an area and/or as an additional source of information to support decision-making about whether to adjust public health measures and directions.[18] A national framework outlining the public health response actions following a detection through wastewater is being developed. Use wastewater testing in this context for early warning, particularly of clusters or outbreaks in areas that have contained transmission and are easing public health restrictions. Wastewater testing is undertaken by RT-PCR and genome sequencing, mainly outside of clinical diagnostic laboratories.

[18] WHO. 7 August 2020. Status of environmental surveillance for SARS-CoV-2 virus - Scientific Brief. https://www.who.int/news-room/commentaries/detail/status-of-environmental-surveillance-for-sars-cov-2-virus

Testing technology	
Epidemiological Zone 2	For screening around a localised outbreak area or screening specific risk settings within a localised outbreak area e.g. residential aged care facilities (RACF), detention facilities. May have some limited utility at the community level in these areas, but considered less useful than in Epidemiological Zone 1.
Epidemiological Zone 3	Not considered useful in this context.

7. Data collection requirements

To understand the amount of testing being conducted for SARS-CoV-2 across Australia, it is crucial to understand the demographic (who is being tested) and the geographic (where testing is occurring) distribution of testing. Central collation and reporting at the national level provide a denominator for calculations of test positivity rates and inform understanding of how equitably testing is being utilised across the community. This information also identifies key demographic groups or geographic regions where increased testing efforts may be required.

Guided by the *Surveillance Plan*, systematic, routine provision of testing data from laboratories to the Australian Government, via jurisdictional communicable disease authorities supports regular reporting to CDNA and PHLN. CDNA and PHLN note the importance and feasibility of collating and reporting on the following information from tests:

- age group
- sex
- geographic region
- test type
- Aboriginal and/ or Torres Strait Islander status.

As guided by the *Surveillance Plan*, the development and implementation of any targeted asymptomatic testing approach should ensure data collection, reporting and evaluation are identified as essential components. The findings, including the value the testing activity adds to the public health response, are important to share nationally, through CDNA, PHLN and AHPPC. Sharing findings will inform the ongoing response by identifying asymptomatic testing approaches of greatest value. Jurisdictional communicable disease authorities, private sector organisations and researchers who may undertake asymptomatic testing activities are encouraged to report on their outcomes. The *Surveillance Plan* contains a reporting template.

8. Key enablers and barriers to testing

8.1 Laboratory capacity

Australia has an expert network of public and private laboratories with the capability and appropriate accreditation to detect SARS-CoV-2. The Australian Government continues to work with pathologists and medical laboratory scientists to ensure:

- availability of testing technologies and methodologies

- testing capacity
- supply of equipment, reagents and test kits
- sustainability of testing
- the highest quality of testing for the Australian community.

8.1.1 Accreditation

The National Association of Testing Authorities, Australia (NATA) together with the Royal College of Pathologists of Australasia assess all Australian pathology laboratories. Laboratories must comply with standards established by the National Pathology Accreditation Advisory Council (NPAAC). They must also meet relevant legal obligations under testing technology-related regulations administered by the Therapeutic Goods Administration (TGA).

To maintain testing accreditation, Australian laboratories are required to participate in a relevant quality assurance program, to ensure SARS-CoV-2 test results are accurate and reliable. The Australian Government supports the Royal College of Pathologists of Australasia Quality Assurance Program Pty Ltd (RCPAQAP) to provide a proficiency testing program (PTP) for SARS-CoV-2. Both PCR and serology PTPs have been offered by RCPAQAP in 2020, and is anticipated to continue.

8.1.2 Maximum Daily Throughput Capacity

Australia has the capability and capacity to meet the current testing demands. However, laboratories' maximum daily throughput cannot increase without:

- procuring new platforms
- training new skilled medical laboratory scientists
- identifying additional laboratory space.

Specially trained scientists are required to operate RT-PCR testing platforms. This workforce is finite.

8.1.3 Supply of testing consumables

The supply of laboratory consumables required for PCR testing such as nucleic acid extraction kits, swabs and personal protective equipment are sometimes limited due to global supply pressures. As there is a limited supply of GeneXpert cartridges, the rapid coronavirus (COVID-19) Remote Point of Care Testing Program for remote and rural Aboriginal and Torres Strait Islander communities and some jurisdictions have developed guidance for rational use. For example *Guidance for the rational use of Point-of-Care Testing in primary care* (Appendix 1 of the *CDNA National Guidance for remote Aboriginal and Torres Strait Islander communities for COVID-19*)[19] and *Rapid testing – NSW Health*[20].

The current continuity of supply into the Australian market of tests and reagents for the primary COVID-19 tests in use is assured. However, supply chains for tests, reagents and

[19] CDNA National Guidance for remote Aboriginal and Torres Strait Islander communities for COVID-19. https://www.health.gov.au/resources/publications/cdna-national-guidance-for-remote-aboriginal-and-torres-strait-islander-communities-for-covid-19

[20] Rapid testing – NSW Health. https://www.pathology.health.nsw.gov.au/covid-19-info/rapid-testing

swabs continues to be monitored. The Australian Government has also invested in securing a strategic reserve of pathology supplies should international supply lines be compromised.

8.1.4 Workforce

The technically skilled pathology collection and laboratory workforces are finite and can easily come under significant pressure in times of increased testing. These workers must maintain additional infection control measures and work split shifts to ensure protection and sustainability of the system. Several laboratories across Australia are currently operating 24 hours a day, seven days per week. This requires laboratory staff to work 12–14 hour shifts at a time. Workforce contingency planning in the event of increased testing demand should include planning for these workforces.

8.1.5 Test request prioritisation within laboratories

PHLN has developed a statement on the prioritisation of diagnostic testing for COVID-19[21]. PHLN encourages decision makers to target testing to strike the right balance between maintaining epidemic control and protecting the sustainability of laboratory capacity. Decision makers may include:

- jurisdictional public health authorities
- senior pathologists
- laboratory managers
- referring practitioners
- approved specimen collection personnel.

This includes, where appropriate, prioritising diagnostic testing requests in line with the priority groups described in this framework, where resourcing and capacity allows.

8.2 Community and clinician engagement

Community engagement is required to ensure high levels of presentation across all sections of the community. Community engagement should target:

1. the general public, to encourage symptomatic people get tested as soon as they develop relevant symptoms
2. health professionals, to encourage the appropriate use of testing against expanded testing criteria.

Messages and modes of delivery must be adapted to the needs of diverse population groups, including consideration of:

- cultural and linguistic diversity and Aboriginal and/or Torres Strait Islander background (this includes translation into language and engaging with trusted community leaders to further disseminate key information using appropriate media)
- health literacy
- occupation
- geographical areas with changing epidemiology, including where SARS-CoV-2 has been detected in wastewater.

[21] PHLN statement on the prioritisation of diagnostic testing for COVID-19 https://www.health.gov.au/resources/publications/phln-statement-on-the-prioritisation-of-diagnostic-testing-for-covid-19

Engaging with key stakeholder bodies is critical to achieve meaningful engagement with long lasting impacts.

Public communications must:

- continue to promote the importance of physical distancing measures for all
- clearly explain the symptoms suggestive of COVID-19
- highlight the need and benefit of getting tested
- highlight how to access testing, including locations, costs, hours of operation, waiting times and steps required before testing and while awaiting results
- highlight respiratory etiquette and the need to minimise contact with people (especially those at high risk for severe disease) until symptoms resolve and test result is known.

Public communication approaches should be underpinned by an understanding of risk perceptions, behaviours and existing barriers, specific needs and knowledge gaps.

Timely and effective communications with health professionals must:

- clearly explain the circumstances in which testing is recommended, and changes to this over time
- highlight occupational groups at greater risk of exposure
- outline how to test safely (i.e. ensuring personal protection)
- explain where patients can access COVID-19 testing, including through private and public laboratories
- provide clear guidance on what restrictions patients should maintain whilst symptomatic and waiting for test results.

8.3 Barriers and disincentives to testing

Barriers and disincentives to testing uptake and access, both perceived and real, must be identified and addressed across diverse population groups. This will ensure that access is equitable and widespread. Barriers and disincentives will vary across the population, but include:

- perceived need: self-assessment of severity or likelihood of symptoms being COVID-19;
- testing fatigue: the need to continue to present for testing, even in extremely low or no prevalence areas;
- the process: expectations of discomfort, inconvenience of having to isolate/stay home after being tested;
- financial: perceived costs of testing including costs of isolation after testing, lack of sick leave arrangements, financial hardship support;
- geographical: proximity to testing sites, especially in rural and remote settings;
- timeliness: hours of operation, requirements to book, waiting times, time to access results;
- cultural sensitivity and acceptance: biases against any community group at testing sites, perceived stigma of getting tested, perceived stigma of a positive test result, fears associated with a positive result (e.g. separation from family);
- safety: perceptions of infection risk by attending health settings to get tested, especially COVID-19 targeted health settings;

- visa and Medicare status: new migrants, bridging and temporary visa holders may not realise they are eligible for free testing even if they do not have a Medicare care card;
- other: implications if positive (especially those with occupations in high-risk settings).

Best practice community engagement, including working with key stakeholder bodies and community surveys, will support a better understanding of potential barriers to access and disincentives to testing and co-development of strategies to address these.

COMMITTEE-IN-CONFIDENCE

Annex A: Current and emerging SARS-CoV-2 testing technology and methods

Executive Summary

The Public Health Laboratory Network (PHLN) and Communicable Diseases Network Australia (CDNA) developed this document. It provides governments, industry and other decision makers with advice on the utility and availability of different SARS-CoV-2 testing technologies and methods:

- that are either available in Australia or emerging globally; or
- may have a role in the COVID-19 pandemic response.

This document describes:

- the different COVID-19 tests and testing methods;
- their evidence for use;
- how accessible and available they are; and
- a high level comparison of test characteristics.

Introduction

The rapid development of new testing technology for SARS-CoV-2 offers Australia the opportunity to explore testing strategies that may be complementary to, although not a replacement for, the gold standard diagnostic test, reverse transcription polymerase chain reaction (RT-PCR). New testing technology and methods with a lower sensitivity than RT-PCR using the traditional throat and bilateral deep nasal (or nasopharyngeal) swab may enable rapid detection of SARS-CoV-2 nucleic acid or viral protein at or near point of care (POC). However, it is important to note that no single test or combination of tests are currently sensitive and reliable enough to detect a person incubating the infection. Therefore, any testing strategy must continue to be considered in addition to other public health control measures.

In writing this document, the PHLN and CDNA consulted with the Peter Doherty Institute for Infection and Immunity (PDI). The PDI is drafting a comprehensive literature review on emerging SARS-CoV-2 testing technology and methods.[1]

The *PHLN Guidance for laboratory testing for SARS-CoV-2* provides detailed guidance on specimen collection and laboratory testing for SARS-CoV-2.

Principles for use

A variety of testing strategies are being considered overseas, but it is not clear how relevant these are to the Australian context, given the vastly different prevalence of SARS-CoV-2. Noting this, PHLN and CDNA advise that in Australia, public health authorities should select COVID-19 tests according to the following principles:

1. In Australia, RT-PCR remains the gold standard test for diagnosing acute symptomatic SARS-CoV-2 infection. However, using alternative tests or testing methods may help conserve the capacity of the public and private laboratory systems.
2. Public health authorities may use alternative testing methods in addition to RT-PCR on respiratory swabs, to facilitate early public health intervention. The purpose of this is to provide earlier indications of any unrecognised chains of community transmission.

3. The use of lower sensitivity tests compared to RT-PCR are only recommended for either public health investigation or screening purposes where the pre-test probability is high. For example contacts of a RT-PCR confirmed case in a close setting, or where community transmission is established.
4. Testing must be done according to public health guidance and/or regulations of the jurisdiction/s involved.
5. The PHLN and CDNA are carefully considering whether there is a role for tests with a lower sensitivity than RT-PCR for frequent screening of asymptomatic persons in high-risk settings (without a link to a confirmed case).
6. Tests with a lower sensitivity than RT-PCR should only be used for routine diagnosis if advised by public health authorities:
    a. in settings where RT-PCR is unavailable; or
    b. where an extensive delay in result turn-around time is anticipated.
7. Public health authorities should consider the potential impact of false negative cases where they use lower sensitivity diagnostic tests during outbreak settings. For example, a small proportion of cases may initially be missed. This may impact public confidence and outbreak control if public health mitigation measures (e.g., quarantine) are not already in place for those being screened with lower sensitivity tests.

1. SARS-CoV-2 Tests

There are two main categories of emerging testing technologies for detection of SARS-CoV-2. Those that:

i. can facilitate high throughput laboratory-based molecular testing; and
ii. are rapid. These broadly include POC SARS-CoV-2 antigen tests, POC antibody tests, and near POC molecular assays.

Assay type[22]	Available literature[23]	TAT	Sensitivity	Specificity	Ease of use at POC	Scalability	Cost	Supply chain
Laboratory-based RT-PCR	+++/++++	Hours	++++	++++	n/a	+++	+++	++/+++
Saliva RT-PCR	+/++	Hours	++/+++	++++	n/a[24]	+++	+++	+++
Rapid or near POC PT-PCR	++++	Under 1 Hour	++++	++++	++	+	++++	+/++
POC NAAT (non-RT-PCR)	+/++	Minutes	+++/++++	++++	++++	+	++++	+/++
Extraction-free LAMP	+/++	Minutes - Hours	++/+++	+++/++++	+	++	+	+++
Extraction-free RT-PCR	+	Hours	+++	++++	n/a	+++	++	++

[22] See below for detailed descriptions of the abbreviated assays
[23] 'Available literature' means peer-reviewed literature or independent evaluation of clinical performance
[24] Specimen collection method may increase ease of use at POC

CRISPR	+	Hours	+++	+++	-	-	+	-
POC Antigen	++	Minutes	++/+++	+++	+++/++++	++	+	-/++
POC Antibody	++	Minutes	+/++	++	++++	++	+++	++

Table 1: High-level comparison of the test characteristics relative to standard RT-PCR.[25][26]

1.1 Nucleic acid amplification testing (NAAT)

NAAT tests detect genetic fragments of SARS-CoV-2 RNA most commonly in an upper respiratory tract specimen. RT-PCR is very sensitive and specific. In Australia, NAAT using RT-PCR is the method of choice to detect SARS-CoV-2 during the acute illness. The Public Health Laboratory Network (PHLN) describes specific guidance for RT-PCR testing in the *PHLN Guidance on laboratory testing for SARS-CoV-2.*

The manufacturer sets the approved specimens for use with a test in the associated Instructions for Use (IFU). Most typically, RT-PCR tests require either a nasopharyngeal, or oropharyngeal and bilateral deep nasal swab. The PHLN advise that the swab can either be collected by:

- Approved Specimen Collection Personnel; or
- the person being swabbed, if appropriate and if the testing method has been validated by the associated laboratory.

Researchers are currently investigating innovative methods for NAAT testing, including:

- sample pooling;
- using saliva as an alternative specimen (to facilitate increased test uptake and more frequent testing on individuals); and
- extraction-free PCR.

Laboratory-based RT-PCR

High throughput, commercial laboratory-based RT-PCR tests are widely available for the detection of SARS-CoV-2. Many pathology laboratories have also developed their own in-house tests to conduct diagnostic testing in Australia.

Evidence for use	Accessibility	Availability
• Peer reviewed papers evaluating the performance. • High sensitivity and specificity • Globally used as the gold standard COVID-19 diagnostic test	• Must be conducted in a NATA/RCPA accredited laboratory by suitably qualified pathologists or medical laboratory scientists. • Requires specialist platforms.	• Capacity may be constrained due to supply chain shortages for consumables. • Capacity may be constrained due to limited throughput of the tests.

Rapid or near POC RT-PCR

Commercial rapid or near POC RT-PCR tests operate similarly to laboratory-based tests, however can determine results within 60 minutes. These tests are not high-throughput and are subject to consumable supply constraints.

[25] Adapted from Graham M, Ballard S, Pasricha A, Lin B, Hoang T, Williamson D, Howden B. Peter Doherty Institute – Literature review on the use of emerging testing technologies and approaches for COVID-19

[26] (-) unknown/insufficient data; (+) minimal; (++) moderate; (+++) high; (++++) very high; (n/a) not applicable; (TAT) turnaround time

Evidence for use	Accessibility	Availability
• Peer reviewed papers evaluating the performance. • High sensitivity and relatively high specificity	• Trained users can use near-POC. • Relatively expensive.	• Capacity constrained due to supply chain shortages for consumables.

POC NAAT (non RT-PCR)

Some commercial POC NAAT tests may be less sensitive than laboratory-based tests, but they claim to determine results within 15-60 minutes. These tests are not high-throughput and are subject to consumable supply constraints.

Evidence for use	Accessibility	Availability
• Moderate number of peer-reviewed papers evaluating the performance (depends on assay). • Moderate to high sensitivity and relatively high specificity	• Trained users can use at POC. • Relatively expensive.	• Capacity may be constrained due to supply chain shortages for consumables.

Extraction-free loop-mediated isothermal amplification (LAMP)

Extraction-free LAMP tests amplify DNA/RNA target sequences at a single reaction temperature. This diminishes the complexity and size of the analysers needed to run testing. Extraction-free LAMP tests aim to provide a rapid and reliable, cheaper alternative to traditional RT-PCR. This rapid test has the potential for use at point of care with medium throughput capability. There appears to be limited published studies of Extraction-free LAMP at POC. Further study is needed to assess how feasible LAMP testing is, particularly with and without an RNA extraction step, requires further study.

Evidence for use	Accessibility	Availability
• Limited peer reviewed studies evaluating the performance.	• Trained users can use at or near-POC.	• Not widely available

CRISPR (Clustered regularly interspaced short palindromic repeats)

CRISPR tests use Cas detection for signal amplification after isothermal amplification of SARS-CoV-2 RNA. These tests require less instrumentation and reagents than RT-PCR, and can be used near-POC. According to manufacturers' IFU and very limited studies, CRISPR may be less sensitive compared to most commercial RT-PCR. Further evaluation is required.

Evidence for use	Accessibility	Availability
• Limited peer reviewed studies available. • IFU declare these tests are highly sensitive and specific.	• Trained users can use at or near-POC.	• No tests on the ARTG.

RT-PCR Innovations

Sample pooling

RT-PCR reagent shortages may limit the expansion of testing required to support Australia's response to the COVID-19 pandemic. Pooling of samples enables an increased test throughput and conserves RT-PCR reagents. It is most efficient where there is low prevalence of disease.

The prevalence of COVID-19 in a population affects the efficiency of pooled testing strategies. In general, lower disease prevalence may enable a laboratory to use a larger pool size. A recent PDI study that found that nucleic acid tests for SARS-CoV-2 reliably returned a positive result when one positive sample was mixed with four negatives. This could reduce the number of tests needed by >50% in certain scenarios (such as a COVID-19 prevalence of <5%). Tens of thousands of samples have undergone SARS-CoV-2 testing in Australia using sample pooling.

Specimens in a pooled procedure are diluted. Therefore the larger the pool of specimens, the higher the likelihood of generating false-negative results.

Saliva as an alternative specimen for RT-PCR

Using saliva as an alternative method for specimen collection for RT-PCR offers a minimally invasive alternative to the throat and bilateral deep nasal (or nasopharyngeal) swab. Recent evaluation studies describe an alternative method for saliva specimen collection using a flocked swab under the tongue. Studies have shown that testing saliva offers a high sensitivity and specificity, albeit less sensitive relative to a nasopharyngeal swab RT-PCR. Australian laboratories are currently validating and using saliva samples for SARS-CoV-2 RT-PCR to facilitate expanded surveillance. Saliva samples are not intended to replace well validated, gold-standard swab-based RT-PCR for diagnosis of disease in symptomatic people.

The majority of COVID-19 RT-PCR tests available on the ARTG are intended for use with a nasopharyngeal/nasal swab. Laboratories have worked to validate a range of swab types for this purpose. If a laboratory wants to use a saliva specimen instead, this is considered 'off label' use and must be validated in accordance with the Therapeutic Goods Administration (TGA) requirements for in-house in-vitro diagnostic devices (IVDs). Therefore, further validation work is required by individual laboratories before saliva may be used widely as an alternative specimen for RT-PCR.

Several reasonably sized studies have shown relatively high sensitivity, but further studies are needed to evaluate the best collection and processing method. Further information is available in the *PHLN statement on use of saliva as an alternative specimen for the diagnosis of SARS-CoV-2*.

Extraction-free PCR

RT-PCR relies critically on the extraction of RNA prior to amplification of nucleic acid. This step takes time and can impact testing turn-around time. It also relies on RNA extraction kits, which have sometimes been in short supply due to global demand. Simplifying the method to remove RNA extraction from the RT-PCR process could:

- decrease the testing turnaround time;
- mitigate supply chain vulnerabilities; and
- reduce test costs.

However, studies have shown that extraction-free PCR has lower sensitivity relative to traditional RT-PCR.

Wastewater

Wastewater surveillance involves analysing wastewater samples for traces of genetic material from disease causing organisms, primarily using RT-PCR. Wastewater surveillance can be used as an early warning signal for the emergence of SARS-CoV-2 in communities where cases have not been detected. This can complement information obtained from clinical testing. In the context of the COVID-19 pandemic, positive COVID-19 cases may shed viral fragments in their

faeces. Wastewater samples may also be positive from used tissues discarded into the wastewater system. Viral fragments can also enter the wastewater network when washed off hands and bodies via basins, sinks and showers.

enHealth and the CDNA are collaborating to share and coordinate testing methods and reporting of wastewater testing for SARS-CoV-2 across Australia.

1.2 Antigen

POC Rapid Antigen

Rapid antigen tests detect viral protein of SARS-CoV-2 in a respiratory tract sample and claim to provide results within 15–30 minutes. This test is typically validated for use with a nasopharyngeal swab.

There is considerable variation between the manufacturers' claimed performance characteristics and performance in the field. This is largely because the majority of rapid antigen tests are intended for use, and validated by the manufacturer, on symptomatic people. Further, most current rapid antigen tests claim that maximal sensitivity is achieved when testing symptomatic individuals, within the first 5-7 days of the onset of symptoms. In general, the sensitivity is lower than for standard RT-PCR tests and performance may vary in the field. This may potentially increase the number of false negative results. It is important to recognise that the sensitivity is an estimate based on testing individuals that are infected as independent events. Where multiple people in a group are infected, such as a household, the pre-test probability will increase. This will influence the positive predictive value of the test and the likelihood of detecting cases. While analytical sensitivity is a function of the IVD, the notion of frequently testing individuals may increase the sensitivity of the process as opposed to increasing the sensitivity of the IVD.

Users should consult their respective public health authority prior to employing rapid antigen tests.

Evidence for use	Accessibility	Availability
• There is considerable variation between the sensitivity and specificity outlined in the manufacturer's instructions.	• Can be conducted at POC. • 10 – 30 tests per hour by a trained medical professional with additional trained staff required for result recording.	• Currently there are 11 RAD tests available on the ARTG for supply to medical professionals. • TGA constraints limit supply to medical practitioners.

The *PHLN and CDNA joint statement on SARS-CoV-2 rapid antigen tests* includes further information.

1.3 Antibody

Serology tests can help identify individuals who have:

- previously had a COVID-19 infection without a RT-PCR diagnosis;
- have had a false negative RT-PCR result; or
- have RT-PCR results that are difficult to interpret.

In addition, serology tests can be used for population-level prevalence studies. Health care professionals take a blood sample using either finger prick or from a vein, to test for antibodies to SARS-CoV-2 as part of an immune response to the virus. However, this response profile is still not completely understood. Therefore, serology results must be interpreted

with caution and in conjunction with clinical presentation by a suitably qualified health care professional, who can provide appropriate advice and treatment if required.

In general, measurable antibody responses are not reliably detected until 14 days or more after COVID-19 disease onset. Noting this delay in the development of antibodies, do not use serology tests as a diagnostic test for acute COVID-19.

The *PHLN guidance on serological testing in COVID-19* has further information on serology testing. This is available on the Department of Health website.

Laboratory-based serology

Most major diagnostic laboratories in Australia, both public and private, have automated high-throughput commercial immunoassay platforms for serological testing for infectious diseases. Serological assays for detection of anti-SARS-CoV-2 antibodies are commercially available in Australia using these platforms. PHLN has conducted a joint, multi-jurisdictional evaluation of several assays, which has been shared with relevant stakeholders, including public health authorities and public and private pathology providers.

Evidence for use	Accessibility	Availability
• Many peer reviewed papers evaluating the performance.	• Must be conducted in a NATA/RCPA accredited laboratory by a medical scientists or pathologists. • Requires specialist platforms.	• Several assays are available on the ARTG.

POC Serology

Lateral flow serology devices are not recommended as first line tests for the diagnosis of acute infection. The performance of these tests is uncertain in the context of Australia's broadly low prevalence setting. They are generally less sensitive than laboratory-based tests. The PDI has so far evaluated 15 serology-based point of care tests. Please refer to most recent results on the TGA website.

Evidence for use	Accessibility	Availability
• TGA post-market evaluation is available online.	• Can be used at POC.	• TGA constraints limit supply to medical practitioners only. • Prohibition on use in several jurisdictions.

1.4 Genomics

Whole genome sequencing (WGS) can be used to reveal the genetic makeup of the virus and detect mutation patterns from different samples. The SARS-CoV-2 RNA mutates slowly and in ways that make very little difference to how infectious it is. However, scientists can use this information to precisely distinguish mutations occurring between and within individuals. By tracking these mutations, viral genomics enables precise and powerful infectious disease surveillance.

By comparing SARS-CoV-2 genomes sequenced from multiple COVID-19 cases, clusters of COVID-19 and transmission of SARS-CoV-2 can be identified. The likely source of infection and routes of transmission can be monitored by the emergence of genetic variants over time and throughout communities. Whole genome sequencing can indicate whether the infection was acquired overseas, or locally from a known or unknown contact. It is also helpful for investigating possible re-infections.

Increasingly, SARS-CoV-2 genomic sequencing is used to enhance surveillance and outbreak investigations across Australia. Currently, six states and territories have the capability to conduct WGS, and support is provided to the other two, while they establish this. Several states are aiming to sequence all positive cases. However, in times of high caseload sequencing will need to be prioritised. In some cases, not enough virus is present in the sample to permit high quality sequencing to be undertaken. The PHLN has published advice on conducting WGS in the *PHLN Guidance on laboratory testing for SARS-CoV-2*.

Evidence for use	Accessibility	Availability
• International peer reviewed studies. • Evidence for use in several Australian jurisdictions to assist in contact tracing.	• Must be conducted in a specialised laboratory. • Turnaround time between 2-5 days.	• Available in six states and territories, with sequencing support provided for the other two.

Recently, manufacturers have designed tests that combine NAAT diagnostic platforms for SARS-CoV-2 with WGS platforms. While these tests offer the possibility of analysing thousands of samples per day on a single platform, there is limited data on their performance at this time.

Conclusion

As the COVID-19 pandemic evolves and more tests and testing methods become available, the Australian Government will continue to update this document. Noting the limited clinical evidence available for performance of some of the COVID-19 tests outlined in this document, the Australian Government advises that where available, these tests must be used in accordance with the following requirements:

1. All commercially supplied tests must be registered for use on the ARTG. Laboratories developing their own tests or using a test 'off-label' (e.g., using alternative samples types) need to comply with the in-house IVD regulatory requirements.
2. Use POC tests following NPAAC Guidelines for Point of Care Testing.
3. Strictly follow the manufacturer's IFU. Using tests outside of these instructions is considered 'off label' use and may compromise the intended testing strategy. The TGA does not recommend or endorse off label use. The user is responsible for any off label use.
4. All positive antigen SARS-CoV-2 results must be confirmed using RT-PCR.
5. Consider all negative tests in the context of clinical observation, the history of the individual and epidemiological information.
6. Facilities intending to deploy POC tests should first notify their jurisdictional public health authority and agree on a protocol for reporting test numbers periodically. This report must include the number of tests conducted (including positives and negatives) to help predict with greater confidence the prevalence of the virus in the community. The facility should report testing numbers at a frequency determined by the jurisdictional public health authority.

References:

1. Graham M, Ballard S, Pasricha A, Lin B, Hoang T, Williamson D, Howden B. Peter Doherty Institute – Literature review on the use of emerging testing technologies and approaches for COVID-19
2. Commonwealth of Australia, National Contact Tracing Review, 13 November 2020