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PHLN
Public Health Laboratory Network

Revised Testing Framework for COVID-19 in Australia March 2022

Revision History

Version	Date endorsed by AHPPC	Revision note
2.1	7 March 2022	Inclusion of Epidemiological Zone 4 and additional updates following National Cabinet meeting of 5 January 2022.
2.0	16 December 2021	Update of whole document.
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1 Background

In Australia, testing to detect SARS-CoV-2 (the virus that causes COVID-19) is, and will continue to remain, a key pillar in the control of COVID-19. As the pandemic evolves, so will testing methods and implementation strategies. Testing enables COVID-19 cases to be identified early and is a critical component of the 'test', 'trace', 'isolate' and 'quarantine' (TTIQ) framework, aimed at reducing community transmission of SARS-CoV-2. This will protect those most vulnerable persons by minimising the risk of serious illness, hospitalisation and death from COVID-19.

We accept that outbreaks will remain a risk. A critical priority of the public health response is to break chains of transmission in the community by rapidly detecting infections, identifying their source and implementing a range of public health measures. Targeted and sustainable testing is crucial to support a rapid and successful outbreak response. Targeted testing also needs to consider the epidemiological setting and vaccination status of the local population. However, when testing capacity is overwhelmed, for example, in the event of a large-scale outbreak, strategies need to adapt to maintain reasonable testing turnaround times and ensure appropriate and timely clinical care can be provided.

1.1 Strategic context

State and territory public health authorities administer testing programs for public health investigation. This document provides a national framework that outlines minimum requirements to guide local approaches to testing. Individual state and territory public health authorities can apply this framework to fit their local circumstances. States and territories are not obligated to adopt this framework; however a consistent national approach is encouraged.

This framework for COVID-19 testing in Australia is updated as required to align with the evolving COVID-19 situation. It is consistent with the COVID-19 [Communicable Diseases Network Australia \(CDNA\) National Guidelines for Public Health Units](#) ('National Guidelines'). It is supported by the [Australian National Disease Surveillance Plan for COVID-19](#), which includes the monitoring of testing rates among its main components.

In addition to this framework, the [Public Health Laboratory Network \(PHLN\) Guidance on Laboratory Testing for SARS-CoV-2](#) outlines testing and specimen collection approaches. The [CDNA National Guidelines for the Prevention, Control and Public Health Management of COVID-19 Outbreaks in Residential Care Facilities in Australia](#) covers managing COVID-19 outbreaks and associated testing in residential care settings, including for aged care and disability care. The [CDNA National Guidelines for remote Aboriginal and Torres Strait Islander communities for COVID-19](#) covers testing in remote communities. The modelling work referred to in this guidance has more information about the potential impact of testing strategies in remote and regional settings.

Finally, serosurveillance is the term used for testing to detect antibodies to SARS-CoV-2 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 described in the [Australian National Disease Surveillance Plan for COVID-19](#).

2 Targeting of COVID-19 testing in Australia

Effective, efficient, and equitable testing needs to focus on:

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

The testing approach must be responsive to change over time. Testing must also strike the right balance between maintaining epidemic control and protecting the sustainability of laboratory and testing site capacity. To be objective-driven and sustainable, this framework outlines approaches to testing in geographical zones categorised according to four 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 3)
- adopting relevant testing methodologies and technologies that best suit the epidemiological context (Section 4).

State and territory governments should consider the best distribution of testing in their own context, for the identified priority groups.

On 30 July 2021, National Cabinet agreed to a plan to transition Australia’s National COVID-19 response from a pre-vaccination setting, focused on continued suppression of community transmission, to a post-vaccination setting focused on preventing serious illness, hospitalisation and fatality consistent with public health management of other infectious diseases. State and territory governments should also consider the best testing strategy in the context of this plan.

As the pandemic evolves, new diagnostic testing technologies for SARS-CoV-2 continue to emerge in the domestic and international markets. This offers Australia the opportunity to investigate testing strategies that may complement gold standard laboratory-based methods. Information and guidance on new testing technology will continue to be included in future revisions of this document as evidence emerges.

PHLN and CDNA members continue to give evidence-based strategic advice on the role and options for use of emerging testing technology to inform Australia’s testing strategy for COVID-19. These advisory groups consider the public health opportunities and the technical benefits and limitations of devices designed to diagnose SARS-CoV-2 infection. Provision of this advice assists to minimise inappropriate use of devices by health or non-health sector users.

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

Annex A contains technical guidance on applying emerging SARS-CoV-2 testing technology in Australia. Health and non-health sector industry groups that do not have expertise should seek expert public health authority advice prior to their use.

3 Testing priorities by Epidemiological Zone and Priority Group

Broadly defined Epidemiological Zones are described in this framework to guide jurisdictions on testing approaches to meet the relevant public health aims. There may be more than one Epidemiological Zone occurring at the same time in a jurisdiction. This requires different, localised approaches to testing and consideration of local vaccination rates. A summary of testing prioritisation is at Table 1, with each Epidemiological Zone addressed in more detail in the sections below.

Table 1. Summary of testing priorities by Epidemiological Zone¹

Priority Group	Epidemiological Zone 1 No community transmission	Epidemiological Zone 2 Community transmission	Epidemiological Zone 3 Community transmission placing burden on response capacity	Epidemiological Zone 4 Community transmission exceeds response capacity
1. People with COVID-19 compatible symptoms	High priority. Particularly important to test patients by gold standard nucleic acid amplification (NAA) testing who present 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. In this epidemiological context, use the gold standard NAA test where available. ²	As per Epidemiological Zone 2.	Testing of people with COVID-19 compatible symptoms should be prioritised. As per Epidemiological Zone 2, however rapid antigen tests may also be used if PCR capacity is overwhelmed to meet the probable case definition, with no requirement to verify result by PCR. Consider reserving laboratory-based NAA testing for symptomatic individuals at higher risk of severe disease and where a result can influence an individual's treatment options (for example, access to monoclonal antibodies).
2. People with known recent exposure to SARS-CoV-2 (asymptomatic)	High priority for those who have known recent exposure to SARS-CoV-2, to support upstream contact tracing where source of infection is uncertain. In this epidemiological context, use the gold standard NAA test where available.	As per Epidemiological Zone 1.	As per Epidemiological Zone 1.	Testing of close contacts should be prioritised, where feasible. Consider using rapid antigen tests instead of laboratory-based NAA to ensure NAA testing turnaround times (TAT) is maintained for Priority Group 1. Refer to National Guidelines for contact definitions and testing requirements.

¹ Some states and territories have enacted public health orders requiring pre-departure nucleic acid amplification (NAA) testing or rapid antigen testing for domestic interstate travel purposes. Laboratory-based testing for this purpose is not recommended in Epidemiological Zone 3. Instead, consideration should be given to the use of rapid antigen testing for this purpose, if required. Consideration should be given to removing any requirement for interstate pre-departure travel testing in Epidemiological Zone 4 due to severe capacity constraints.

² Availability should be defined by both an individual's physical accessibility (both geographically or logistically) to a NAA test, as well as a tests average testing turnaround time (TAT). An appropriate TAT will be where a result can be received in time to achieve appropriate clinical management of an individual.

Priority Group	Epidemiological Zone 1 No community transmission	Epidemiological Zone 2 Community transmission	Epidemiological Zone 3 Community transmission placing burden on response capacity	Epidemiological Zone 4 Community transmission exceeds response capacity
3. People at higher risk of exposure to SARS-CoV-2 (asymptomatic)	<p>High priority for returning overseas travellers and for people working in areas that places them at an increased risk of exposure to SARS-CoV-2 (for example, at the border or supporting quarantine programs).</p> <p>In this epidemiological context, use the gold standard NAA test where available.</p>	<p>As per Epidemiological Zone 1, with the addition of testing high-risk groups based on unexplained onset of non-respiratory or non-specific symptoms. Please refer to the National Guidelines for more information.</p> <p>In this epidemiological context, use the gold standard NAA test where available.</p>	<p>As per Epidemiological Zone 2.</p>	<p>Consider use of rapid antigen tests. Laboratory-based NAA testing is not recommended.</p> <p>Use rapid antigen tests for any industry-led workplace screening, especially those who are classified as “critical workforce”. Screening that relies on NAA testing is not recommended.</p>
4. People in high- and special-risk settings, including where disease amplification in a setting is likely (asymptomatic)	<p>High priority for high-risk settings where risk of amplification is high.</p> <p>In this epidemiological context, use the gold standard NAA test where available.</p>	<p>As per Epidemiological Zone 1, with the addition of testing around a single case or outbreak and public health-led routine screening.</p> <p>In this epidemiological context, use the gold standard NAA test where available.</p>	<p>Laboratory-based testing is prioritised for people who have a higher risk of more severe disease outcomes.</p> <p>In this epidemiological context, use the gold standard NAA test where available.</p> <p>Put on hold any industry-led workplace screening that is laboratory-based. Consider rapid antigen testing.</p>	<p>Consider use of rapid antigen tests. Laboratory-based NAA testing is not recommended.</p> <p>Use rapid antigen tests for any industry-led workplace screening, especially those who are classified as “critical workforce”. Screening that relies on NAA testing is not recommended.</p>

3.1 Priority groups for testing

As shown in Table 1, this framework identifies four priority groups for targeted testing in Australia. The emphasis on particular priority groups differs across Epidemiological Zones to meet the aim of the public health response.

As the pandemic evolves, these priority groups are subject to change. Once a high level of population immunity is achieved, it is recommended that jurisdictions manage COVID-19 consistent with the public health management of other common respiratory diseases by minimising the spread of cases within the community. However, even with high levels of vaccine uptake, we do not expect vaccination will achieve a high level of population immunity for all SARS-CoV-2 variants, for example, the highly transmissible Omicron variant. Therefore, the composite three levers to control the spread of the virus remain vaccination, public health and social measures (PHSM) alongside TTIQ.

The current priority groups are:

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. However, where laboratory testing capacity is overwhelmed, consider preserving laboratory-based tests for those where greater characterisation of the virus by whole genome sequencing (WGS) will inform a patient's treatment plan (i.e., those at higher risk of severe disease).

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. In settings with no or low community transmission, consider routine testing strategies or monitoring contacts for symptom development that could be consistent with COVID-19 and encourage prompt referral for testing if symptoms develop (Priority Group 1). For this Priority Group, please refer to the [National Guidelines](#) for the most up-to-date recommendations relating to the testing of close contacts.

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
- who care for people with COVID-19 or
- who have contact with people who are more likely to have an active infection as part of their regular work.

In epidemiological zones where there is no or limited community transmission, groups identified as being at increased risk of exposure to SARS-CoV-2 infection include, but are not limited to:

- international border staff
- workers supporting quarantine and isolation services

- air and maritime crew or
- health care workers and aged care workers with direct patient contact.

Depending on the epidemiological context, casual and mobile workers who work across multiple settings (for example, cleaners, rideshare service and taxi drivers, construction workers, security personnel) may also have an 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) or
- 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 others who have an increased risk of severe disease and death.

In areas of increased community transmission that places a burden on (Epidemiological Zone 3), or overwhelms (Epidemiological Zone 4) laboratory capacity, Priority Group 4 would become a higher priority than Group 3. 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 near others or
- with specific environmental conditions.

These settings may include, but are not limited to:

- health care settings
- residential aged care settings
- residential care settings
- primary schools
- 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.

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](#).

3.2 Epidemiological Zones

Four epidemiological zones have been defined to reflect the range of community transmission rates a jurisdiction may experience throughout the evolution of the pandemic; from no community transmission (Epidemiological Zone 1) to high community transmission causing the health pathology sector to become overwhelmed (Epidemiological Zone 4).

The current Epidemiological zones are defined below.

3.2.1 Epidemiological Zone 1 – No community transmission

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

Testing focus

The aim in this Epidemiological Zone is to increase confidence that:

- SARS-CoV-2 transmission is not continuing undetected, and
- any imported cases in the community are quickly identified, to initiate a move to 'outbreak response' as quickly as possible.

Detecting 'zero' COVID-19 cases with confidence requires extremely 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.

Encourage people with COVID-19 compatible symptoms and with known recent exposure to SARS-CoV-2 to promptly present for testing. This continues to be important even in extremely low prevalence contexts. Encourage testing 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, if there is unknown community transmission. In geographical areas where wastewater testing detects the presence of SARS-CoV-2, 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. If there is no disease in the area, the greatest risk is at the border. Placing returning international travellers in quarantine and testing when entering and leaving quarantine, 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.

Until we reach a high level of population immunity (assuming this is achievable), asymptomatic screening is important to detect unrecognised cases early, as borders open and travel increases. In particular, regular, routine testing of workers in COVID-19 quarantine and isolation settings is recommended. Test workers who are at high risk of exposure at a frequency determined by the epidemiological context. Please refer to Section 4 for advice on suitable testing technology and methodology for each Epidemiological Zone.

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

3.2.2 Epidemiological Zone 2 – Community transmission

Epidemiological context - *Sporadic cases and clusters, through to wide-spread community transmission, with laboratory testing meeting testing demand.*

Testing focus

The aim in this Epidemiological Zone is to identify active cases to reduce further spread of infection in the defined area, while vaccination rates continue to increase. 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 in the community, encourage everyone with COVID-19 compatible symptoms to present for testing as soon as possible after symptom start (Priority Group 1). This is particularly important in areas with community transmission where there may be concern for potentially undetected chains of transmission, and where there are low community vaccination rates. Encourage anyone with symptoms compatible with COVID-19 or who is assessed as close contacts to be tested by reverse-transcriptase polymerase chain reaction (RT-PCR).

Close contacts who remain asymptomatic throughout their quarantine period (Priority Group 2) must 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 when they enter and (if appropriate) leave quarantine, or if symptoms of COVID-19 develop during quarantine. The National Guidelines give further detail on timing of this testing.

Upstream contact tracing³ 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, especially if an asymptomatic case presents with no history of vaccination⁴.

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 non-respiratory or non-specific symptoms is supported, based on clinical and public health judgement. Non-respiratory or non-specific symptoms may include fatigue, muscle pain, joint pain, diarrhoea, nausea/vomiting and loss of appetite, without accompanying acute respiratory infection symptoms. Please refer to the National Guidelines for more information.

Consider testing of asymptomatic people 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:

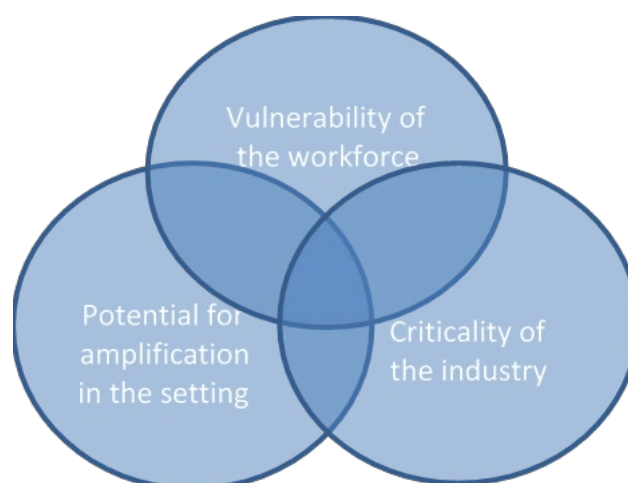
- identify the source of introduction
- identify the scope of an outbreak
- help early detection of pre-symptomatic cases and mitigate further transmission
- minimise the duration of isolation/quarantine experienced by people with ongoing close contact.

In this epidemiological context, the National Guidelines outlined 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 in the setting) until safe to return.

³ Upstream contacts are individuals who are potential sources of infection for a particular case, with contact in the incubation period of the case and the infective period of the contact.

⁴ Serology (antibody) testing is not considered appropriate for the diagnosis of active acute infection, as these tests detect an individual's immune response to the virus, with maximum effectiveness at approximately 14 days post-onset.

In all phases, public health-led, routine asymptomatic testing in high- and special-risk settings can be valuable in this epidemiological context. This has the potential to quickly find the infection in these settings. Testing in strategically selected industries or workplaces can act as a bridge to communities otherwise difficult to reach. Consider these elements when selecting workplaces or industries:



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 authority.

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

Epidemiological context - *Wide-spread community transmission, with testing demand placing a burden on laboratory capacity.*

Testing focus

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

When disease is widespread, laboratory testing 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 cases⁵) is critical to ensure the efficiency and effectiveness of the case isolation and contact tracing process.⁶ Rapid notification of confirmed cases will ensure downstream transmission risk is mitigated as quickly as possible.

TATs are dependent on:

- the timeliness of specimen transport from the collection site to the laboratory
- laboratory-specific resources
- the level of testing demand on any given day

⁵ A confirmed case requires laboratory definitive evidence (i.e., detection of SARS-CoV-2 by NAA)

⁶ Commonwealth of Australia. National Contact Tracing Review. 13 November 2020. <https://www.health.gov.au/resources/publications/national-contact-tracing-review>

- the needs of specific patient populations according to local priorities
- integration of technology
- a laboratory's use of specimen pooling⁷ and
- result distribution method.

TATs increase when testing rates surge or need to be maintained at a high level over a long period. 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.

Encourage people with COVID-19 compatible symptoms (Priority Group 1) to present as soon as possible after symptoms start. This 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. Consider further rationalisation of testing if TATs continue to increase, for example, limit testing to close contacts who become symptomatic (Priority 1) while in quarantine or begin to use alternative testing methods such as rapid antigen tests (RATs) to supplement laboratory-based testing methods.

Testing of people at risk of exposure and people in high and special-risk settings remains consistent with Epidemiological Zone 2. If there are laboratory capacity constraints, prioritise laboratory-based testing of these groups to people who have a higher risk of more severe disease outcomes. Consider using RATs for other priority groups in these circumstances.

When laboratory capacity constraints exist, asymptomatic laboratory-based testing not led by public health authorities should be stopped. For example, put workplace COVID-19 employee testing programs that are laboratory-based, on hold until the constraints have eased. In this situation consider screening with rapid antigen testing devices.

3.2.4 Epidemiological Zone 4 – Community transmission exceeding response capacity

Epidemiological context - *Wide-spread community transmission, with testing demand exceeding laboratory capacity.*

Testing focus

The aim of this Epidemiological Zone is to preserve laboratory testing and maximise the outcomes of public health efforts by prioritising testing of symptomatic individuals, especially those at a higher risk of experiencing severe disease.

In this epidemiological context, laboratory testing is overwhelmed. Conservation of TAT is critical to ensure the efficiency and effectiveness of the public health response and to inform appropriate management of an individual at higher risk of severe disease. Individual

⁷ Pooling samples involves combining specimens from different patients together in a "pool", then testing the pooled sample to detect the presence of a virus. Detection of viral nucleic acid then requires individual retesting of patient specimens. This approach increases the number of specimens that can be tested and can also increase testing efficiency and reduce the overall cost of testing. However, efficiency gains of pooling strategies depend on the prevalence of infection. It is recommended that pooling strategies are adopted when the prevalence in the population is low.

contact tracing is not feasible in this context. There is a shift to a case-directed contact tracing and patient-centred clinical management paradigm.

Encourage people with COVID-19 compatible symptoms (Priority Group 1), especially those who are at a higher risk of severe disease to present for NAA testing as soon as possible after symptoms start. This will ensure timely access to whole genome sequencing and targeted treatment options.

Consider using alternative testing technologies such as RATs for other priority groups to relieve pressure on the pathology system. As per the National Guidelines, in this epidemiological context, a positive RAT result will not require a confirmatory NAA test and should be treated as a probable case. A negative result from a RAT must be considered in the context of an individual's clinical history, clinical observation, and epidemiological information. Where a symptomatic person presents a negative RAT result, they should always have a follow-up test (either RAT after 24 hours or NAA, depending on accessibility and priority of individual). Persons with negative results should not be assumed to be non-infectious and a negative result must not be used to negate the need for other appropriate interventions (such as mask-wearing and physical distancing).

Testing of asymptomatic contacts (Priority Group 2) and asymptomatic individuals at higher risk of exposure (Priority Group 3), including workplace screening not led by public health authorities, and testing as part of interstate travel requirements is not recommended. In this situation consider screening with rapid antigen testing devices if required.

Laboratory-based NAA testing of people in high and special-risk settings should be reserved for symptomatic individuals, or asymptomatic individuals where there has been a confirmed positive case in that setting and transmission is likely. Reserve point-of-care NAA tests, including RT-PCR, to symptomatic individuals in settings where they are deployed to confirm an index case.

While NAA testing should be reserved for symptomatic cases, asymptomatic cases (known recent exposure) where NAA testing may be required include:

- Remote and rural communities with low prevalence to identify cases early
- High-risk settings (for example, residential aged care facilities) to identify an index case, or to determine the extent of an outbreak, or
- Cases at high-risk of severe disease (for example, immunosuppressed individuals) who may be eligible for monoclonal antibody therapy.

In addition, RAT-positive cases where confirmatory NAA testing may be required include:

- Cases at high-risk of severe disease (for example, immunosuppressed individuals) who may be eligible for monoclonal antibody therapy
- RAT-positive critical workers (for example, healthcare workers) to confirm need for furlough, or
- Initial index case in high-risk settings to confirm an outbreak before triggering an outbreak response plan.

4 Testing technology and methodology by Epidemiological Zone

All viruses, including SARS-CoV-2, change over time as part of their natural evolution. This change may impact on the diagnostic accuracy of the test. In Australia all testing methodologies have been comprehensively validated and continue to be closely monitored

by the Therapeutic Goods Administration (TGA) and by laboratory personnel, through mandatory participation in quality assurance program modules that have been developed specifically for SARS-CoV-2 and its variants.

<i>Testing technology</i>	
Laboratory-based RT-PCR	
Epidemiological Zone 1	<p>Gold standard diagnostic test, critical for identifying current infection.</p> <p>In occupational and vulnerable population settings, consider using more acceptable collection methods (for example, saliva as a specimen), where these are validated⁸, for easier administration and repeat testing. Also consider employing pooling strategies⁹ when the prevalence or pre-test probability is low.</p> <p>PHLN recommends the use of multiplex RT-PCR assays that detect SARS-CoV-2 and other commonly circulating respiratory viruses, where resourcing and laboratory workflows allow, to conserve resources and ensure optimal surveillance.</p> <p>Specimen pooling <u>will help conserve RT-PCR</u> testing consumables and laboratory capacity. These methodologies need laboratory validation. Seek PHLN advice on current availability and utility.</p>
Epidemiological Zone 2	<p>Reserved for symptomatic testing, upstream contact tracing and testing close contacts (symptomatic and asymptomatic).</p> <p>As per Epidemiological Zone 1, consider using more acceptable collection methods, where validated.</p> <p>Specimen pooling strategies <u>may no longer</u> be appropriate as prevalence or pre-test probability rises. Consult PHLN for advice on pooling implementation. Pooling is not always appropriate.</p>
Epidemiological Zone 3	<p>Reserved for symptomatic testing and upstream contact tracing when TATs exceed 24 hours at the 90th percentile.</p> <p>As per Epidemiological Zone 1, consider using more acceptable collection methods, such as saliva, where validated.</p> <p>Pooling strategies are <u>unlikely to be viable</u> in this epidemiological context as prevalence or pre-test probability likely to be too high. Consult PHLN for advice on pooling implementation.</p>
Epidemiological Zone 4	<p>In this epidemiological context, consider preserving laboratory-based RT-PCR testing for symptomatic individuals only (Priority Group 1), especially those at higher risk of severe disease and asymptomatic people in high and special-risk settings (Priority Group 4) where a confirmed case has already been identified and transmission is likely.</p> <p>As per Epidemiological Zone 1, consider using alternative collection methods, where validated. Pooling strategies are <u>not viable</u> in this epidemiological context as prevalence or pre-test probability is too high.</p>

⁸ Please refer to the *PHLN statement on using saliva as a respiratory specimen for SARS-CoV-2 testing* for more information.

⁹ 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.

Point-of-care RT-PCR for example GeneXpert, Cobas LIAT, BioFire FilmArray	
Epidemiological Zone 1	<p>Use point-of-care RT-PCR systems in settings where laboratory-based testing is not available or a rapid TAT to result is needed. This might be in rural and remote communities or hospital intensive care units. This enables current infection to be identified early.</p> <p>These systems are low throughput and expensive.</p> <p>It is preferred that POC RT-PCR is used in Aboriginal and Torres Strait Islander communities to confirm the first case in a community.</p>
Epidemiological Zone 2	As per Epidemiological Zone 1.
Epidemiological Zone 3	As per Epidemiological Zone 1.
Epidemiological Zone 4	In this epidemiological context, consider preserving point-of-care RT-PCR testing for symptomatic individuals (Priority Group 1), especially those at risk of more severe disease and asymptomatic people in high and special-risk settings (Priority Group 4) where a confirmed case has already been identified and transmission is likely.
Laboratory-based serology (antibody) tests	
Epidemiological Zone 1	<p>Reserved for where the result will influence individual patient or outbreak management, such as:</p> <ul style="list-style-type: none"> • Patients who have had symptoms before that are 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. • Upstream contacts of a case with uncertain epidemiological links. • 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. <p>A positive antibody detection on a rapid (or laboratory-based) serology test does not correlate to immunity and protection from COVID-19.</p> <p>Unless clinically indicated, routine serology testing is not recommended post-vaccination to determine an individual's antibody response profile.</p> <p>Refer to the PHLN guidance on laboratory testing for SARS-CoV-2 (the virus that causes COVID-19) to understand other appropriate contexts for use.</p>
Epidemiological Zone 2	As per Epidemiological Zone 1
Epidemiological Zone 3	<p>As per Epidemiological Zone 1</p> <p>Limited utility in this context. Seek advice from pathology provider for appropriate application.</p>
Epidemiological Zone 4	As per Epidemiological Zone 3.
Rapid antigen testing at the point-of-care	

Epidemiological Zone 1	<p>Rapid antigen tests are not recommended for widespread use in low-risk settings (for example low prevalence environments where an individual is unlikely to be exposed to SARS-CoV-2, or where there is no community transmission).</p> <p>Seek advice from a local jurisdictional public health authority on using rapid antigen tests in outbreak settings.</p>
Epidemiological Zone 2	<p>Where the pre-test probability is high, rapid antigen tests may have a role for public health investigation. For example, for regular repeat surveillance testing or urgent triage of vulnerable high-risk individuals.</p> <p>This technology may prove useful as a screening test for individuals in high risk settings (that is, high risk of exposure/transmission, or severe disease outcomes) or as a workplace screening measure to ensure business continuity.</p> <p>It offers rapid results in relevant settings, while reducing pressure on RT-PCR capacity. Positive detections need RT-PCR for confirmation and sequencing as appropriate. RT-PCR testing is also recommended for individuals that return a negative rapid test result but have symptoms compatible with COVID-19.</p> <p>See Annex A for more information on the benefits and limits of rapid antigen tests.</p>
Epidemiological Zone 3	<p>As per Epidemiological Zone 2.</p> <p>In this epidemiological zone it is expected that there will be a greater business interest in the implementation of workplace screening programs using rapid antigen tests. This may be as part of a supervised program or at home testing, in accordance with TGA requirements. Consideration may also be given to their use for interstate domestic travel pre-departure or post arrival travel purposes.</p>
Epidemiological Zone 4	<p>In this epidemiological zone, consider rapid antigen tests for symptomatic (Priority Groups 1) and close contacts (Priority Group 2).</p> <p>Conserve NAAT capacity (both laboratory-based and point-of-care) for Priority Groups 1 and Priority Group 4 (where a confirmed case has already been identified and transmission is likely), as defined in Section 3.2.4.</p> <p>A positive rapid antigen test result does not need to be confirmed by NAAT-based testing methods. A person that tests positive on a rapid antigen test meets the definition of a probable COVID-19 case. For more information, please refer to the National Guidelines.</p>
Rapid non-RT-PCR nucleic acid amplification tests (NAAT) (that is, LAMP tests) at the point-of-care (or near point of care)	
Epidemiological Zone 1	<p>Rapid non-RT-PCR NAAT are not recommended for widespread use in low prevalence environments. They may be useful in outbreak settings.</p>

Epidemiological Zone 2	<p>Where the pre-test probability is high, rapid non-RT-PCR NAAT may have a role in public health investigations. For example, regular repeat surveillance testing or urgent triage of vulnerable high-risk individuals when the chosen device has been properly calibrated by a public health reference laboratory against RT-PCR.</p> <p>This technology may prove useful as a screening test for individuals in high risk settings (that is, high risk of exposure/transmission, or severe disease outcomes) or as a workplace screening measure to ensure business continuity.</p> <p>It offers rapid results while reducing pressure on RT-PCR capacity. Positive detections would need RT-PCR for confirmation and sequencing as appropriate. RT-PCR testing is also recommended for individuals that return a negative rapid test result but have symptoms compatible with COVID-19.</p> <p>PHLN recommends the use of multiplex RT-PCR assays that detect SARS-CoV-2 and other commonly circulating respiratory viruses, where resourcing and laboratory workflows allow, to conserve resources and ensure optimal surveillance.</p> <p>See Annex A for more information on the benefits and limitations of rapid non-RT-PCR NAAT.</p>
Epidemiological Zone 3	As per Epidemiological Zone 2. However, for a symptomatic individual where an initial RAT is negative, consider undertaking a repeat RAT (after 24 hours) where NAA is not available.
Epidemiological Zone 4	<p>In this epidemiological context, consider reserving non-RT-PCR NAAT for:</p> <ul style="list-style-type: none"> • symptomatic individuals (Priority Group 1), especially those at risk of more severe disease • asymptomatic people in high and special-risk settings (Priority Group 4) where there has been a confirmed positive case in that setting and transmission is likely, and • exceptions as listed in Section 3.2.4.
Genomic sequencing	
Epidemiological Zone 1	Genomics can differentiate between SARS-CoV-2 strains introduced from overseas or interstate and local transmission and can help to identify a source or index case. Genomics is also important for monitoring virus evolution. In this epidemiological context, the <u>aim is to sequence every positive case</u> .
Epidemiological Zone 2	May be used for new local outbreaks to identify links that cannot be confirmed epidemiologically. The aim in this epidemiological context is to <u>sequence every positive case</u> . Some prioritising may be needed depending on capacity.

Epidemiological Zone 3	<p>To support the collection of timely and accurate information from SARS-CoV-2 genomic surveillance, including detection of variants in this epidemiological zone, the Communicable Diseases Genomics Network (CDGN)(an expert reference network of PHLN) has developed the Sampling strategy for SARS-CoV-2 genomic surveillance (the Strategy).</p> <p>The Strategy outlines an approach for genomic surveillance from <i>comprehensive sequencing</i> (in Epidemiological Zones 1-2) to <i>selective and targeted sequencing</i> (in Epidemiological Zone 3-4), balancing the utility and cost of real-time SARS-CoV-2 genomic surveillance in the environment of the rapid spread of a dominant strain of the virus.</p> <p>The aim in this epidemiological context should be to prioritise the sequencing of cases in line with the CDGN Strategy, depending on local capacity.</p>
Epidemiological Zone 4	<p>As per Epidemiological Zone 3.</p> <p>The aim in this epidemiological context should be to prioritise the sequencing of cases suspected of harbouring a new variant of interest or concern, in line with the CDGN Strategy (for example, international arrivals confirmed as being a positive case), monitor the prevalence of a given variant in the community and to monitor virus evolution in severely immunocompromised cases.</p>
Testing methodology	
Wastewater testing (RT-PCR or genomic sequencing)	
Epidemiological Zone 1	<p>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.¹⁰ The <i>National SARS-CoV-2 Wastewater Surveillance Operational Guidance</i>¹¹ details how wastewater epidemiology adds to SARS-CoV-2 surveillance and informs public health actions at the jurisdictional and national levels.</p> <p>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.</p> <p>Wastewater testing is done by RT-PCR and genome sequencing, mainly outside of clinical diagnostic laboratories.</p>
Epidemiological Zone 2	<p>For screening around a localised outbreak area, detecting new outbreak areas or screening specific risk settings in a localised outbreak area for example residential aged care facilities (RACF), detention facilities, and public housing.</p> <p>May have some limited use at the community level in these areas, but considered less useful than in Epidemiological Zone 1.</p>
Epidemiological Zone 3	<p>May have some limited utility at the community level in these areas but considered less useful than in Epidemiological Zone 2. In this context, there may be sufficient genomic material to enable more successful whole genome sequencing from wastewater to help monitor for genomic variations as the outbreak evolves.</p>

¹⁰ 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>

¹¹ To be made publicly available on the Department of Health website in early 2022.

Epidemiological Zone 4	Not recommended except in specific use cases, such as to detect emerging variants of concern in jurisdictions with the capability to do so.
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5 Workplace surveillance

COVID-19 screening by testing is one element of a suite of PHSM that may protect business continuity and allow potential COVID-19 cases to be identified early.

CDNA, PHLN and the Australian Health Protection Principal Committee (AHPPC) recommend regular asymptomatic testing of staff working in areas that places them at an increased risk of exposure to SARS-CoV-2 in Epidemiological Zones 1 to 3. For example, COVID-19 quarantine facilities and high-risk healthcare settings¹². This will support and protect the wellbeing of staff and the wider community.

Several industries have introduced programs for COVID-19 testing of staff as a screening measure to:

- ensure staff and customer safety and
- reduce the risk of COVID-19 being introduced into the workplace as a business continuity measure.

This testing framework outlines where screening testing is best targeted to inform the public health response, based on four Epidemiological Zones (Section 3).

There are critical principles and requirements that employers should consider before deciding to start a COVID-19 employee testing program outside of public health-led testing programs. Importantly, a COVID-19 employee testing program should be part of a suite of measures to ensure a complete approach to COVIDSAFE business continuity planning.

Employers without in-house expertise should consult with relevant health experts to develop targeted workplace screening approaches, including staff testing programs.

Employers need to consider, at minimum:

- how the testing program will be carried out, including who will run the program and be responsible for the capture and secure reporting of results to the executive and, if requested, to public health authorities (if not laboratory-based)
- whether self-testing at home before work is a suitable approach and whether there is a need to capture and verify results
- who will be tested and how often will they be tested
- local public health reporting and investigation protocols
- how employers will manage testing of staff who are on leave or off shift
- what type of screening test or testing platform(s) will be used, for example, self-testing, point of care or laboratory-based (for advice on suitable testing technology and methodology for each Epidemiological Zone, please refer to Section 6)
- identifying staff with COVID-19 compatible symptoms so they can be appropriately managed

¹² 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>

- if using non-laboratory-based point-of-care tests, how positive detections (sometimes referred to as a non-negative detection) on screening tests will be managed
- how to manage staff rights such as safety, leave entitlements and privacy
- financial implications for employers
- communication and process for standing up and standing down the workplace testing program and
- whether the testing program will be voluntary or mandatory.

Widespread low priority testing may increase laboratory turnaround times (TAT) for high priority testing. If there are laboratory capability and capacity constraints, suspend routine COVID-19 employee testing programs that rely on laboratory-based testing.

Where supply chain shortages exist for rapid antigen tests, similar consideration should be given to suspend low priority testing using rapid antigen tests.

6 Testing reimbursements

From 1 January 2022 until 30 June 2022, the Australian Government has extended the temporary Medicare Benefits Schedule (MBS) items 69479 and 69480 for NAA testing for COVID-19. From this date, the MBS item (69501) for COVID-19 screening of asymptomatic essential workers will cease.

A reduced schedule fee for MBS items 69479 and 69480 will apply from 1 January 2022, reflecting a reduction in the cost of providing COVID-19 tests.

A request from a medical or nurse practitioner is a requirement for MBS items 69479 and 69480. Rebates must only be claimed where a patient's treating practitioner determines that the test is necessary for the clinical management of their patient.

All COVID-19 tests undertaken for public health screening purposes, for example, asymptomatic screening, will continue to be provided free-of-charge through state and territory public health testing sites. Public health testing sites can be found via the relevant state and territory health department websites. More information can be found on the [MBS website](#).

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
- geographic (where testing is occurring) distribution of testing.

Central collation and reporting at the national level provides a denominator for calculating test positivity rates and informs an understanding of how equitably testing is being implemented and accessed across the community. This information also identifies key demographic groups or geographic regions where increased testing efforts may be required.

Guided by the [Australian National Disease Surveillance Plan for COVID-19](#) (the Surveillance Plan), the Australian Government receive systematic, routine testing data from laboratories via jurisdictional communicable disease authorities.

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 and
- Aboriginal and/ or Torres Strait Islander status.

As guided by the Surveillance Plan, any screening (asymptomatic) testing approach is recommended to include data collection, reporting and evaluation.

Sharing findings informs the ongoing response by identifying asymptomatic testing approaches of greatest value. We encourage jurisdictional communicable disease authorities, private sector organisations and researchers who undertake screening testing activities 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 and to securely capture and report results. The Australian Government continues to work with pathology providers to ensure:

- availability of testing technologies and methodologies
- testing capacity
- infection prevention
- supply of equipment, reagents and test kits
- sustainability of testing and
- the highest quality of testing for the Australian community.

8.2 Accreditation

All Australian pathology laboratories must comply with the specified standards in the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2017* to be eligible to provide MBS-rebatable pathology services. The National Pathology Accreditation Advisory Council (NPAAC) develops and maintains accreditation standards. If an Australian pathology laboratory develops their own test, they must also meet relevant legal obligations under the [Therapeutic Goods \(Medical Device\) Regulations 2002](#). This is administered by the TGA.

To maintain testing accreditation, Australian laboratories must participate in a relevant quality assurance program, to monitor performance and 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. The RCPAQAP develops and offers both RT-PCR, serology and genomics PTPs.

8.3 Maximum Daily Throughput Capacity

Australia has the laboratory capability and capacity to meet the testing demands, including asymptomatic testing, for Epidemiological Zones 1 and 2. In Epidemiological Zone 3, this finite capacity may be strained and in Epidemiological Zone 4 it will be overwhelmed.

Laboratory-based RT-PCR testing may need to be reserved for symptomatic individuals and upstream contact tracing when TATs take more than 24-hours. The maximum daily laboratory-based testing throughput cannot increase without:

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

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

8.4 Supply of testing consumables

The supply of laboratory consumables needed for RT-PCR testing such as nucleic acid extraction kits, swabs, rapid antigen tests and personal protective equipment are sometimes limited because of global supply pressures. Similarly, there is a limited supply of rapid point-of-care nucleic acid amplification tests (NAAT), which are commonly used in emergency departments and to support the rapid COVID-19 Remote Point of Care Testing Program for remote and rural Aboriginal and Torres Strait Islander communities. Conscious of these supply constraints, several jurisdictions have developed guidance for rational use. For example the [*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*) and [*Rapid testing – NSW Health*](#).

The Australian Government continues to monitor supply chains for tests, reagents and swabs. The Australian Government continues to monitor and replenish, where appropriate, its strategic reserve of medical supplies to mitigate any risk of international supply issues.

8.5 Workforce

The technically skilled pathology collection and laboratory workforces are finite. They can come under significant pressure in times of increased testing and have an increased risk of being furloughed. These workers must maintain extra infection prevention measures and work split shifts to protect and sustain service delivery. Several laboratories across Australia are operating 24 hours a day, seven days per week. This means laboratory staff are working 12–14-hour shifts at a time. In times of increased testing demand, workforce contingency planning must include planning for these workforces.

8.6 Test request prioritisation in laboratories

PHLN has developed a [*statement on the prioritisation of diagnostic testing for COVID-19*](#). 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, and when aligned with the National Plan.

As described above, CDGN has also developed the [Sampling strategy for SARS-CoV-2 genomic surveillance](#). Decision-makers need to consider prioritising COVID-19 samples for referral for sequencing in line with this advice.

8.7 Community and clinician engagement

Community engagement is needed 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 COVID-19 compatible symptoms and
2. health professionals, to encourage appropriate testing against expanded testing criteria.

Adapt messages and modes of delivery to the needs of diverse population groups. Consider:

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

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

Public communications must:

- continue to promote how important physical distancing measures are for all
- clearly explain the symptoms suggestive of COVID-19
- highlight the benefit of getting tested, especially those who are symptomatic (Priority Group 1)
- highlight how to get tested, including locations, costs, hours of operation, waiting times and steps required before testing and while awaiting results and
- 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.

Plan public communication approaches on an understanding of risk perceptions, behaviours and existing barriers, specific needs and knowledge gaps.

Timely and effective communication with health professionals must:

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

9 Barriers and disincentives to testing

Identify and address barriers and disincentives to testing uptake and access, both perceived and real, across diverse population groups. This will support equitable and widespread access. 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 testing
- financial: perceived costs of testing including 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 receive 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, fear of a positive result (for example 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, and
- other: implications if positive (especially for people with occupations in high-risk settings).

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

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 use 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 complement 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 allow rapid detection of SARS-CoV-2 nucleic acid or viral protein at or near point of care (POC). No single test or combination of tests are currently sensitive and reliable enough to detect a person incubating the infection. Public health control measures will continue to be needed with any testing strategy.

In writing this document, the PHLN and CDNA consulted with the Peter Doherty Institute for Infection and Immunity (PDI). The PDI has published a comprehensive literature review on emerging SARS-CoV-2 testing technology and methods¹³.

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

Consider any testing strategy in the context of the COVID-19 disease prevalence in Australia at any given time and community vaccination rates. PHLN and CDNA advise that in Australia, public health authorities should choose a COVID-19 testing approach using these principles:

1. In Australia, RT-PCR remains the gold standard test for confirming a diagnosis of acute active SARS-CoV-2 infection. Using alternative tests or testing methods for screening may help conserve the capacity of the public and private laboratory systems for testing of symptomatic or high-risk individuals.

¹³ Graham M, Ballard SA, Pasricha S, Lin B, Hoang T, Stinear T, Druce J, Catton M, Sherry N, Williamson D, Howden BP. Use of emerging testing technologies and approaches for SARS-CoV-2: review of literature and global experience in an Australian context. *Pathology*. 2021 Oct;53(6):689-699.

2. Public health authorities may use alternative testing methods and RT-PCR on respiratory swabs, to facilitate early public health intervention. The purpose of this is to give earlier indications of any unrecognised chains of community transmission.
3. The use of lower sensitivity tests compared to RT-PCR are 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 closed setting, where community transmission is known, or in workplace screening programs.
4. Conduct testing in line with public health guidance and/or regulations of the jurisdiction/s involved.
5. Only use tests with a lower sensitivity than RT-PCR 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 likely.
6. Public health authorities should consider the potential impact of false negative results where they use lower sensitivity rapid tests during outbreak settings. For example, some cases may initially be missed. This may impact public confidence and outbreak control if public health mitigation measures (for example quarantine) are not already in place for those being screened.

1. SARS-CoV-2 Tests

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

- i. High-throughput and
- ii. Rapid, point of care (for example, rapid antigen tests, antibody tests, and molecular assays)

Table 1: High-level comparison of the test characteristics relative to standard RT-PCR.¹⁷¹⁸

Assay type ¹⁴	Available literature ¹⁵	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 ¹⁶	+++	+++	+++
Rapid or near POC RT-PCR	++++	Under 1 Hour	++++	++++	++	+	++++	+ / ++
POC NAAT (non-RT-PCR)	+ / ++	Minutes	+++ / ++++	++++	++++	+	++++	+ / ++
Extraction-free LAMP	+ / ++	Minutes - Hours	++ / +++	+++ / ++++	+	++	+	+++
Extraction-free RT-PCR	+ / ++	Hours	+++	++++	+	+++	++	++
CRISPR	+	Hours	+++	+++	-	-	+	-
POC Antigen	++	Minutes	++ / +++	+++	+++ / ++++	++	+	++
POC Antibody	++	Minutes	+ / ++	++	++++	++	+	++

¹⁴ See below for detailed descriptions of the abbreviated assays

¹⁵ 'Available literature' means peer-reviewed literature or independent evaluation of clinical performance

¹⁶ Specimen collection method may increase ease of use at POC

¹⁷ 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

¹⁸ (-) unknown/insufficient data; (+) minimal; (++) moderate; (+++) high; (+++++) very high; (n/a) not applicable; (TAT) turnaround time

1.1 Nucleic acid amplification testing (NAAT)

NAAT detect nucleic acid sequences specific to SARS-CoV-2 RNA most commonly in an upper respiratory tract specimen. RT-PCR (one type of NAAT) 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. Refer to the [PHLN Guidance for laboratory testing for SARS-CoV-2](#) for RT-PCR testing.

The manufacturer sets the approved specimens for use with a test in their 'Instructions for Use' (IFU). Most RT-PCR tests need 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
- swabbing by the person, if appropriate and:
 - if the testing method is validated by the associated laboratory and
 - under health care practitioner supervision.

Innovative methods for NAAT include:

- sample pooling (when test positivity in the population is low)
- using saliva as an alternative specimen (to help increased test uptake and more frequent testing on individuals) and
- extraction-free PCR.

Where available, PHLN recommends the use of multiplex assays that detect SARS-CoV-2 and other commonly circulating respiratory viruses, to conserve resources and ensure optimal surveillance.

Laboratory-based RT-PCR

High throughput, commercial laboratory-based RT-PCR tests are widely available to detect 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
<ul style="list-style-type: none"> • Peer reviewed papers evaluating the performance. • High sensitivity and specificity. • Globally used as the gold standard COVID-19 diagnostic test. 	<ul style="list-style-type: none"> • Must be done in a NATA/RCPA accredited laboratory by suitably qualified medical laboratory scientists supervised by a pathologist. • Requires specialist platforms. 	<ul style="list-style-type: none"> • Capacity may be constrained because of supply chain shortages for consumables. • Capacity may be constrained because of high demand where widespread community transmission established

Rapid or near point-of-care (POC) RT-PCR

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

Evidence for use	Accessibility	Availability
<ul style="list-style-type: none"> • Peer reviewed papers evaluating the performance. • High sensitivity and relatively high specificity. 	<ul style="list-style-type: none"> • Trained users can use near-POC. • Relatively expensive. 	<ul style="list-style-type: none"> • Capacity constrained because of supply chain shortages for consumables.

POC NAAT (non-RT-PCR)

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

Evidence for use	Accessibility	Availability
<ul style="list-style-type: none"> • Small to moderate number of peer-reviewed papers evaluating the performance (depends on assay). • Moderate to high sensitivity and relatively high specificity. 	<ul style="list-style-type: none"> • Trained users can use at POC. • Relatively expensive. 	<ul style="list-style-type: none"> • Capacity may be constrained because of 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 give a rapid and reliable, cheaper alternative to traditional RT-PCR. This rapid test has the potential for use at POC 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
<ul style="list-style-type: none"> • Limited peer reviewed studies evaluating the performance (depending on the assay). 	<ul style="list-style-type: none"> • Trained users can use at or near-POC. 	<ul style="list-style-type: none"> • Not widely available. • Some tests are included on the Australian Register of Therapeutic Goods (ARTG).

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 need 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 needed.

Evidence for use	Accessibility	Availability
<ul style="list-style-type: none"> • Limited peer reviewed studies available. • IFU declare these tests are highly sensitive and specific. 	<ul style="list-style-type: none"> • Trained users can use at or near-POC. 	<ul style="list-style-type: none"> • No tests on the ARTG.

RT-PCR Innovations

Sample pooling

RT-PCR reagent shortages may limit the expansion of testing needed 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 allow 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 negatives¹⁹. 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. If a manufacturer has not validated their RT-PCR test for use with pooled specimens the laboratory must validate this use according to the TGA regulatory requirements for in-house in-vitro diagnostic medical devices (IVDs). The laboratory will also need to validate use of alternative pool sizes from that intended by a manufacturer.

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, although is less sensitive relative to a nasopharyngeal swab RT-PCR. Many Australian laboratories have validated using saliva samples for SARS-CoV-2 RT-PCR to facilitate expanded surveillance and acceptability of collection method. Saliva samples are not intended to replace well validated, gold standard swab-based RT-PCR for diagnosis of active acute SARS-CoV-2 infection.

The majority of SARS-CoV-2 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 plans to use a saliva specimen instead of the swab sample validated by the manufacturer, they must validate this according to the TGA regulatory requirements for in-house IVDs. Therefore, individual laboratories must further validate work before using saliva 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 for saliva. More 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 RNA extraction before 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 because of 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

¹⁹ Chong, Brian SW, et al. "Sample pooling is a viable strategy for SARS-CoV-2 detection in low-prevalence settings." *Pathology* 52.7 (2020): 796-800.

information obtained from clinical testing. In the context of the COVID-19 pandemic, positive COVID-19 cases may shed genetic material in their faeces. Wastewater samples may also be positive from used tissues discarded into the wastewater system. Genetic material can also enter the wastewater network when washed off hands and bodies through basins, sinks and showers.

enHealth and CDNA are collaborating to share and coordinate testing methods and reporting as well as the associated public health messaging in response to wastewater testing for SARS-CoV-2 across Australia.

enHealth's Water Quality Expert Reference Panel (WQERP) has developed a national framework for wastewater testing and reporting. The CDNA working group is currently developing complementary guidance for public health action and surveillance.

1.2 Antigen

POC Rapid Antigen

Rapid antigen tests detect viral protein of SARS-CoV-2 in a respiratory tract sample and give results in 10–30 minutes. This test is typically validated for use with a range of upper respiratory tract specimens or in some cases, saliva.

The manufacturers' claimed performance characteristics and performance vary considerably in the field. This is largely because most 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, in the first 5-7 days of the onset of symptoms. The sensitivity of antigen tests 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.

Evidence for use	Accessibility	Availability
<ul style="list-style-type: none"> There is considerable variation between the sensitivity and specificity outlined in the manufacturer's instructions. 	<ul style="list-style-type: none"> Can be conducted at POC. 10 – 30 tests per hour by a trained health care practitioner or trained person under their supervision. More trained staff are needed for result recording. From 1 November 2021, have been available for home use. 	<ul style="list-style-type: none"> TGA sets conditions for supply and use. As of 1 November 2021, at home self-testing is now available in Australia.

The [PHLN and CDNA joint statement on SARS-CoV-2 rapid antigen tests](#) includes more information.

1.3 Antibody

COVID-19 antibody testing is a serological test (blood test) that uses a blood sample to identify IgM and IgG antibodies, to determine whether a person may have been infected with COVID-19 in the past. These tests can be laboratory-based or performed using rapid POC 'fingerprick' tests. This technique can be used to diagnose a previous infection but is not recommended to diagnose a current infection.

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 give 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 antibody development, serology tests are not recommended for use as a diagnostic test for acute COVID-19.

The [PHLN Guidance on laboratory testing for SARS-CoV-2](#) has more information on serology testing.

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
<ul style="list-style-type: none"> • Many peer-reviewed papers evaluating the performance. 	<ul style="list-style-type: none"> • Must be done in a NATA/RCPA accredited laboratory by a medical scientists or pathologists. • Requires specialist platforms. 	<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • TGA post-market evaluation is available online. 	<ul style="list-style-type: none"> • Can be used at POC. 	<ul style="list-style-type: none"> • TGA sets conditions for supply and use. • 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. Scientists can use this information to distinguish mutations occurring between and in individuals. By tracking these mutations, viral genomics enables precise and powerful infectious disease surveillance. It is especially critical for the detection of existing and emerging SARS-CoV-2 variants of concern, such as Alpha, Delta, Beta and Omicron.

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. WGS 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, most states and territories have the capability to conduct WGS, and support is provided to those developing it. In Phase A, B and C of the National Plan, an attempt to sequence every positive case was preferred. However, in times of high caseload sequencing, samples were prioritised based on jurisdictional priorities. 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](#).

To support the National Plan, and as we move into a post-vaccinated society, the CDGN has developed the [Sampling strategy for SARS-CoV-2 genomic surveillance](#) (the Strategy). The Strategy outlines an approach for genomic surveillance from comprehensive sequencing to selective and targeted sequencing, balancing the utility and cost of real-time SARS-CoV-2 genomic surveillance in the environment of the rapid spread of a dominant strain of the virus, and ability of the genomic data to show variations within clusters given the relative stability of the SARS-CoV-2 genome.

Evidence for use	Accessibility	Availability
<ul style="list-style-type: none"> International peer reviewed studies. Evidence for use to assist in contact tracing. 	<ul style="list-style-type: none"> Must be conducted in a specialised laboratory. TAT between 2-5 days. Some jurisdictions have additional capability for rapid turn-around of urgent sequencing requests. 	<ul style="list-style-type: none"> Available in most states and territories, with sequencing support provided to those developing capability.

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 currently.

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 according to these requirements:

1. All commercially supplied tests must be registered for use on the ARTG.
2. Follow [NPAAC Guidelines for Point of Care Testing](#).
3. Use of the POC tests must be in strict accordance with the manufacturer's instructions for use. Using the test outside the manufacturer's instructions may compromise the intended testing strategy and breach TGA regulations in relation to supply and use of these tests.
4. Consider all negative tests in the context of clinical observation, the history of the individual and epidemiological information.