Rapid Antigen Testing Principles

Summary

In Tasmania the recommended approaches to testing have been evolving and will continue to evolve under the guidance of the Communicable Disease Network Australia (CDNA), the Public Health Laboratory Network (PHLN), and the Australian Health Protection Principal Committee (AHPPC).

Detecting cases of COVID-19 through testing for SARS-CoV-2 using reverse transcription-polymerase chain reaction (RT-PCR) is a critical strategy of the Tasmanian Government in controlling transmission of COVID-19 in the community. Testing is a key component of the national approach to surveillance of COVID-19.

Rapid antigen tests are point-of-care tests that allow for detection of SARS-CoV2 antigens within a 15–30 minute window. Most tests are performed on nasal swabs.

Whilst these tests provide a rapid result, there are significant issues with sensitivity and specificity. They are not an appropriate testing strategy in a community with no, or minimal, circulating COVID-19 or for testing asymptomatic individuals outside of supervised screening programs. Furthermore, they are resource intense and not suitable for high volume testing. Importantly, all rapid antigen testing performed on symptomatic individuals, whether positive or negative, must be confirmed by RT-PCR test.

In specific settings, rapid antigen testing may complement and preserve, but not replace RT-PCR testing once community prevalence of COVID-19 increases. Anyone presenting with symptoms that are consistent with COVID-19, regardless of how mild, continue to be encouraged to undergo testing using the gold standard of RT-PCR.

Trials for the appropriate use of rapid antigen testing are currently being undertaken in Victoria, New South Wales and Australian Capital Territory. The results of these trials will assist Tasmania in the implementation of effective surveillance programs in high-risk settings once community transmission is established.

Background

The primary test utilised in Australia for the diagnosis of SARS-CoV-2 is a nucleic acid test, usually RT-PCR. These are the gold standard for diagnostic testing in SARS-CoV-2. As the pandemic has evolved, there has been a need to contemplate alternate testing technologies and methodologies and how they might be utilised to complement the existing response. To that end, there is ongoing consideration and investigation as to the suitability of utilising rapid antigen testing for the purpose of COVID-19 surveillance.

The Public Health Laboratory Network, in conjunction with the Communicable Diseases Network Australia, have produced guidance on the use of Rapid Antigen Testing in Australia (see PHLN and CDNA joint statement on SARS-CoV-2 rapid antigen tests (health.gov.au) for further details).

As of 28 October 2021, the Therapeutic Goods Administration has approved twelve COVID-19 rapid antigen self-tests for use in Australia (see COVID-19 rapid antigen self-tests that are approved in Australia | Therapeutic Goods Administration (TGA) for further details).
What is a Rapid Antigen Test?

A rapid antigen test is a point-of-care (or near person care) testing technology that has a turn-around-time from swab to result of approximately 15 – 30 minutes. Although less sensitive than RT-PCR testing, if used repeatedly and within an appropriate epidemiological context, rapid antigen tests may be considered a suitable technology for surveillance screening purposes.

Rapid antigen testing technology has a lesser sensitivity compared with RT-PCR (meaning that someone with disease may test negative via a rapid antigen test who would otherwise test positive on RT-PCR) and when used in a setting with little to no community transmission, rapid antigen tests may also be less specific (meaning that someone without disease may test positive). Repeated and frequent use of rapid antigen testing may ameliorate some issues with sensitivity by detecting individuals at onset of infection and lead to a greater likelihood of accurately identifying potential SARS-CoV-2 infections.

To be used in Australia, a rapid antigen test must be registered on the ARTG and be supplied in accordance with the conditions prescribed in the Therapeutics Goods Administration (TGA). They must be used in accordance with the National Pathology Accreditation Advisory Council (NPAAC) Guidelines for Point of Care (POC) Testing and used in strict accordance with manufacturer’s instructions for use. There needs to be the suitable procedures and protocols in place to ensure competency amongst testing staff, with acceptable quality practices and with established equipment maintenance practices.

Most rapid antigen tests require collection of a nasal swab. A small number of saliva antigen tests have been approved.

Limitations of Rapid Antigen Test use

Rapid antigen tests are generally less sensitive and are less specific compared to RT-PCR, resulting in falsely negative or positive results. A Cochrane review suggested that where COVID-19 prevalence in community is <0.5%, asymptomatic screening would result in 70-90% of positive rapid antigen tests being falsely positive.

This review also found that rapid antigen tests failed to identify between 30–50% of infections.

The clinical utility and efficacy of a screening program changes as community COVID-19 case numbers change.

In terms of the Public Health response to COVID-19, use of rapid antigen tests outside of a laboratory or clinical environment may result in:
- failure to notify public health of a presumptive positive result
- failure to consider the need for RT-PCR testing
- failure to undertake confirmatory RT-PCR testing for a presumptive positive result
- failure to undertake confirmatory RT-PCR testing for a presumptive negative result from a symptomatic individual
- incomplete data capture and reporting of presumptive positive and negative results to public health
- inappropriate communication of unconfirmed rapid antigen test results.
Current National recommendations for the use of Rapid Antigen Testing

Currently, rapid antigen testing is only appropriate as part of an outbreak investigation where there is a high pre-test possibility (considering the wider epidemiological context) or to rapidly identify if COVID-19 may be the cause of a respiratory illness outbreak in a contained setting (such as mining sites).

Trials are currently being undertaken nationally to investigate the best use of rapid antigen testing in the following situations:

- as an interim measure where PCR testing is likely to be unacceptably delayed (such as a remote community setting)
- as part of a regular workplace screening program (i.e., not one off testing, but routine testing at regular intervals)
- as part of a program to increase students attending face to face school-based education as part of an outbreak response
- as part of a screening program for staff and visitors to high risk setting such as Residential Aged Care Facilities and Health Care Facilities.

Rapid antigen testing should not be considered for use in:

- testing of close or casual contacts
- substituting for RT-PCR in symptomatic individuals where PCR testing is easily and readily available
- areas where there is low prevalence of COVID-19 cases
- routine home-based testing.

Considerations for use in Tasmania

Non-clinical workplace screening programs

A rapid antigen testing screening program is the testing of a specific cohort (such as by a workplace/employer), who are asymptomatic, on a regular basis, with the express purpose of identifying any potential undiagnosed cases of COVID-19.

There has been significant interest throughout Australia as to the potential use of rapid antigen tests to be an effective tool to assist in screening employees at a place of work to provide reassurance of suitability to work without risk of transmitting COVID-19 in that setting.

Several jurisdictions already have industrial and school-based workplaces that have implemented rapid antigen testing surveillance programs, and these are constantly being modified as more experience is gained in the best use of these tests.

There are limited benefits to be gained from the implementation of a rapid antigen test surveillance screening program in a low-prevalence community setting. While there is little to no community transmission, there is greater benefit to be gained from employers utilising COVID-Safe work practices.
Non-clinical settings that have engaged rapid antigen testing screening programs in other jurisdictions include:

- mining sites
- residential aged care facilities
- food supply related businesses
- major banks (Westpac and Commonwealth Bank both have trial testing programs)
- for the management of events
- transportation and freight (WA in conjunction with RT-PCR)
- ports of entry (including maritime and air)
- hotel quarantine
- construction
- travel-related (international aircrew entering VIC require a rapid antigen test pre-departure)
- retail settings.

**Clinical workplace screening programs**

Rapid antigen testing has been implemented in several institutional settings where a rapid result is required. Implementation in these settings requires a healthcare workforce trained in the use of the tests, and the rapid antigen testing must be used in accordance with NPAAC guidelines for POC testing.

Implementation of a rapid antigen test screening program should not be undertaken in a low-prevalence community setting.

Clinical settings that have engaged rapid antigen testing screening programs in other jurisdictions include:

- hospitals – including within specific areas such as Emergency Departments.
- non-hospital clinical settings – including General Practitioner practices/medical centres, laboratory services.

**School-based screening programs**

There is ongoing consideration as to the suitability and benefits from utilising rapid antigen testing amongst both teachers and students during outbreak scenarios in school and educational settings.

As of November 2021, New South Wales is undertaking pilot programs that review the potential role for rapid antigen testing amongst school students who are close contacts of confirmed COVID-19 cases as well as the role of rapid antigen testing in schools as part of a community surveillance initiative.

Other countries have instituted routine rapid antigen testing amongst students and teachers on a bi-weekly (England) or fortnightly (Singapore) basis.

Public Health will continue to review evidence as it becomes available and support the development of tailored plans that take into consideration the unique setting of Tasmanian schools and educational institutions.

Public Health will continue to liaise with the Department of Education to establish suitable programs for both screening and surveillance.
Home use

Home use tests can be purchased from pharmacies, supermarkets, other retail outlets and online. Only rapid antigen tests approved by TGA should be used. These are listed on the TGA website: https://www.tga.gov.au/covid-19-rapid-antigen-self-tests-are-approved-australia.

Due to the lack of training or experience by users, home-use rapid antigen tests are not as accurate as those performed in a health-care setting:

- if a home test is positive an individual must isolate and have a PCR test as soon as possible
- if a home test is negative but an individual still has symptoms, they should have a PCR test.

Home tests are not currently recommended in Tasmania.

Anyone with symptoms of COVID-19 should ring the Public Health Hotline or see their GP to get a RT-PCR test.

Use amongst travellers

At this stage, rapid antigen tests are not considered a suitable test type to satisfy the requirements of a ‘negative test within 72 hours prior to travel’ to allow vaccinated individuals to enter Tasmania without requiring quarantine.

Key messages

Rapid antigen tests should only be used when there is sustained community transmission of COVID-19. Rates between 3–5% community prevalence of COVID-19 have been used in other states and territories as an indicator for the use of rapid antigen tests.

Rapid antigen tests should only be used as a screening tool for COVID-19 asymptomatic individuals in clearly defined screening programs supported by Public Health.

All workplace screening programs (including school-based) must be supervised by a health practitioner and have clear guidelines, which include:

- the choice of test and procedures for optimal results (including appropriate specimen testing and handling)
- infection prevention and control procedures
- management of a positive test result
- notification of a positive result to Public Health
- management of symptomatic staff who have a negative rapid antigen test
- process for recording and reporting all results
- a determination of which staff are to be tested and how often
- HR considerations, including contractual, safety and privacy rights.

All workplaces should have an up-to-date COVID-19 Safety Plan, and, for priority settings and large workplaces, a Case and Outbreak Management Plan. For more information go to www.coronavirus.tas.gov.au/business-and-employees/covid-19-case-and-outbreak-management