NSW GOVERNMENT Health

Framework for the Provision of Rapid Antigen Screening for COVID-19 in Clinical and Non-Clinical Settings

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For use by	This document provides guidance for Rapid Antigen COVID-19 Screening in clinical and non-clinical sites in NSW during the COVID-19 response. These guidelines recognise that individual facilities will need to tailor their response to local patterns of disease and available resources. For those industries, schools and other non-health care settings this document provides high level guidance. These guidelines should be used to support pandemic planning for the COVID-19 response.

Framework for the Provision of Rapid Antigen Screening for COVID-19 in Clinical and Non-Clinical Settings

1. Purpose

This Framework has been developed to guide the delivery of high quality, safe and appropriate Rapid Antigen Screening for COVID-19 non-clinical and clinical settings in order to:

- Support uptake of frequent COVID-19 testing in high priority settings
- Increase the proportion of people who can access frequent testing
- Reduce the number of people with undiagnosed COVID-19 infection in priority settings.

2. Background

NSW Health has implemented a range of measures to promptly identify cases of COVID-19 infection and prevent transmission in NSW, including rapid antigen screening and conventional laboratory (PCR) testing.

Should a person in NSW be confirmed to have COVID-19 infection, NSW Health has procedures in place to identify people they have been in close contact with. Those people are provided with advice about self-isolation to minimise spread of infection.

The NSW Government is committed to working with industry, aged care facilities and schools in a phased approach to introduce rapid antigen screening, to mitigate against outbreaks in workplaces and schools.

Where it is not possible to undertake testing at a particular site, such as on school grounds, a range of other screening options can be explored to detect COVID-19. This includes PCR testing, point of care PCR testing and highly pooled saliva/PCR screening.

Rapid antigen screening is another tool to support the pandemic response but does not replace the usual mask-wearing, hand hygiene and distancing rules that need to remain in place, as well as the need for vaccination and ongoing education of the community. This includes not coming to work or school if unwell, isolating if instructed to by NSW Health and, where necessary, verbal screening of people to ensure they have not attended a venue of concern.

The rapid antigen test is quick and easy. It involves a nasal swab (using a small cotton bud-like instrument) that is then placed into a chemical solution and the solution is tested on the receptacle, which displays a result within 10-15 minutes. This link provides an overview of how the test works.

Rapid antigen screening can be performed onsite in selected workplaces and schools under appropriate supervision to ensure advice is available on the process for testing and how the result is interpreted.

Rapid antigen screening is one pathway to increase testing for COVID-19; particularly for people who reside and/or work in a priority setting. The addition of rapid antigen screening to the mix of options in NSW increases access to screening for COVID-19 as well as provides extra convenience to people who are required to test more frequently.

3. When rapid antigen screening may be appropriate

Rapid antigen tests performed at frequent intervals have been used internationally and in Australian industries for some time as an indicative screen for COVID-19 in their asymptomatic employees.

If a person has flu-like symptoms or is a close or casual contact for COVID-19, rapid antigen screening should not be used, and the person should be directed immediately for a laboratory-based PCR test for COVID-19. The location of PCR testing sites across NSW can be found here.

Frequent rapid antigen screening can reduce the number of new infections in the community, especially amongst people who do not show any symptoms. To maximise the public health benefit, screening 2–3 times per week is recommended.

The benefits of rapid antigen screening are relative to the amount of disease that is present in a population (prevalence), with greater benefit from settings with high prevalence. At low levels of prevalence, the risk of having a false-positive test results will exceed the public health benefit.

Although these tests have some limitations when compared to the nose and throat swabs undertaken with a laboratory PCR test, rapid antigen screening can be performed easily and onsite with results available within minutes.

The choice of target populations and how tests are performed are important considerations. Mass screening in samples of the population alongside contact tracing can focus the containment effort in affected communities and can assist with relaxing lockdown restrictions.

4. Service Model

a. Therapeutic Goods Administration approved tests

Only rapid antigen test devices registered by the Therapeutic Goods Administration (TGA) can be used for COVID-19 testing in Australia. Screening must be conducted in accordance with any product specific conditions placed on the test by the TGA. Information on registered tests and conditions is available from the TGA website.

Please note that in line with current TGA advice, self-testing at home remains prohibited. TGA recommends that testing should be performed in conjunction with a health practitioner who can conduct or oversee the performance of the testing and provide immediate clinical advice if required. Conditions of supply for rapid antigen tests and supervision requirements are set out on the TGA website.

b. NSW Health reviewed devices

A list of rapid antigen testing devices that have been reviewed by NSW Health is available on the NSW Health website. The key quality and performance criteria for assessing rapid antigen test devices includes affordability, sensitivity, specificity, user-friendliness, time to result and whether the device is robust.

5. Use of rapid antigen tests

Rapid antigen testing for COVID-19 should be used as a **screening test** and is not suitable for use as a **diagnostic test**. Rapid antigen screening should be conducted 2-3 times per week with individuals in identified priority settings.

A person who receives a positive rapid antigen test result needs to have an urgent PCR test on a second collection to determine whether COVID-19 is in fact present. When a person has a positive rapid antigen test result, they must be notified immediately to NSW Public Health on 1300 066 055. The Public Health

Unit will advise on safe transport to a local COVID-19 testing facility where the person will have priority access to a PCR test.

The person with a positive rapid antigen test result must remain in isolation until a definitive result is available.

Where a person declines a rapid antigen test at their place of work or school, then it is recommended that they do not enter the site until they can provide evidence of a recent negative COVID-19 test. A recent COVID-19 test result is considered a result from within the previous 72 hours.

Information on what supports for people who live in NSW and cannot earn an income because they must self-isolate or quarantine or are caring for someone with COVID-19 can be found here.

6. Sites for rapid antigen testing

Rapid antigen testing is designed to be done in a range of sites including non-clinical and clinical settings.

Examples of non-clinical settings include construction sites, educational institutions, fixed and temporary community-based sites, aged care residential facilities and commercial businesses such food production sites.

Interested industries and schools are invited to review the Standard Operating Procedure set out below and use the TGA recommended devices as set out on the TGA and NSW Health websites.

General procedures for how to use a testing device are set out on the Appendices of this document.

NSW Health recommends following the manufacturer's instructions for the kits purchased as individual devices may vary. Procedure examples provided by NSW Health are as indication of how the test kits are used generally.

7. Conditions for the provision of safe and high-quality rapid antigen screening

Provision of safe and high-quality rapid antigen screening requires that:

- The testing environment is fit for purpose. All equipment is in good working order, all procedures are carried out accurately, efficiently and safely and the wellbeing and confidentiality of the individual is respected, especially in relation to test result.
- The Standard Operating Procedure set out below for rapid antigen screening in NSW is adopted by sites providing rapid antigen screening for COVID-19 (inclusive of clinical and non-clinical settings). The Standard Operating Procedure includes:
    - establishing appropriate clinical governance
    - the standard workplace health and safety assessment
    - information on administering a test and delivering a test result
    - establishing a mechanism for confirmatory testing for individuals who receive a positive test result
    - reporting of data to NSW Health as requested.
- All health practitioners and persons under their supervision must be trained in the correct use of the device and the interpretation of the test results. A health practitioner remains responsible for the conduct of testing and must be available to provide assistance or advice as required to persons under their supervision in the correct use of the device and the interpretation of the test results.

8. Evaluation and Monitoring

Appropriate evaluation and monitoring must be undertaken for each site providing rapid antigen testing for COVID-19.

This is essential to support best clinical practice and for monitoring the impact and outcomes of implementing rapid antigen testing for COVID-19 in NSW.

Details around the type of information to be collected and reported is set out in the Standard Operating Procedure.

Standard Operating Procedure
for the Provision of Rapid Antigen Screening for COVID-19 in Clinical and Non-Clinical Settings

OVERVIEW

Rapid Antigen COVID-19 screening sites can be established to mitigate against outbreaks in workplaces, aged care facilities and schools as well as increasing local testing capacity. This document provides guidance on how to establish a COVID-19 screening site safely and efficiently during the COVID-19 response.

OBJECTIVES

The objectives of establishing a rapid antigen COVID-19 screening site include:

- To promote early detection of community-acquired COVID-19 cases by maintaining a testing schedule for individuals every 2-3 days; and
- To support and encourage workers in industry and students in schools to get tested by making testing access easy and convenient.

Establishing Rapid Antigen Testing COVID-19 screening sites can provide increased testing capacity to areas of need, promote testing in areas with low testing rates and to mitigate against outbreaks in priority settings including workplaces, aged care facilities and schools.

Rapid antigen screening is one pathway to increase testing for COVID-19; particularly for people who reside and/or work in a priority setting. The addition of rapid antigen screening to the mix of options in NSW increases access to screening for COVID-19 as well as provides extra convenience to people who are required to test more frequently.

LOCATION

Rapid Antigen COVID-19 screening sites are located on a safe and easily accessible site.

The officer responsible for each site will need to determine the suitability of the proposed Rapid Antigen COVID-19 testing location to ensure it is both safe and easily accessible. It will also need to be sign posted so workers and students can find it easily and are appropriately spaced while waiting to be tested.

Signage and instructions about social distancing, checking in and checking out and mask-wearing can be downloaded from the NSW Health website to assist with consistent messaging. General and industry specific materials, as well as translated materials are also available.

If it is determined that a location may be suitable for a Rapid Antigen COVID-19 screening site, a site checklist (see Appendices) should be completed to ensure other relevant factors have been considered prior to set-up. The chosen site should be monitored and checked daily for any environmental changes.

The Key Questions below should be considered when determining the suitability of the site.

- Is there access to utilities including power, wi-fi and water?
- Is the site mobility friendly (if required)?
- Is the site well-lit?
- Consider security of any equipment/structures that may be left unattended after-hours.
- Are there staff amenities within proximity including a toilet (both male and female)?
- Does the site offer weather protection e.g. ability to erect awning or marquee for sun, wind and rain during testing?

MANAGEMENT OF SITES

Rapid Antigen COVID-19 screening sites are run safely and efficiently.

The officer responsible will need to ensure site governance is established and communicated to workers and students and the health professionals and supervisors overseeing the testing process.

The Key Questions below should be considered for safe and effective management of site staff who are undertaking and supervising the testing process.

- Is there an agreed orientation process for all health professional and supervising staff to the site?
- Is their sufficient staff mix to ensure wait times for workers and students is minimised and allowance for staff breaks?

  [The ratio of health practitioners to people under their supervision will vary from site to site depending on the size and complexity of the site as well as the experience of the staff in performing the test. To give guidance to organisations implementing rapid antigen testing, based

on advice from industries already using the technology, one health practitioner is required per 40 workers. For example, a site that has 200 individuals needing to be screened, will require five (5) health practitioners on site to supervise tests. This advice will be updated regularly based on feedback from the pilot sites to assist other sites with their planning to schedule testing times and avoid congestion.]

- Are all health professional and supervising staff aware of the need to correctly use Personal Protective Equipment (PPE)? And is enough PPE available including surgical masks, surgical gloves and a safe disposal process for waste materials?
- Is their suitable hand sanitising stations for workers and students set up to avoid congestion?
- Are QR codes clearly established to assist with the check in and check out process and spaced sufficiently to avoid congestion?

VULNERABLE POPULATIONS

Provide Rapid Antigen COVID-19 screening in a culturally safe manner.

COVID-19 testing is a core strategy in limiting the spread of COVID-19 in the NSW population. It is vital that all parts of the population can access testing when appropriate. With regards to Rapid Antigen COVID-19 testing, vulnerable populations may include Aboriginal and Torres Strait Islander communities, people from culturally and linguistically diverse (CALD) backgrounds and those who may have mobility issues or other special needs.

The Key Questions below should be considered to support Rapid Antigen COVID-19 testing for vulnerable populations.

- Is there an opportunity for members of the Aboriginal health workforce to be trained to perform swabs?
- Are testing sites in the area mobility friendly? Particularly where students and workers are known to have mobility issues.
- Have opportunities to promote COVID-19 testing within existing health activities for vulnerable populations been considered and implemented?
- Is translated material available as required to assist with messaging?

SIGNAGE AND COMMUNICATIONS

The screening clinic has clear signage indicating the Rapid Antigen COVID-19 screening site's location and instructions for users whilst on site.

The officer responsible will need to ensure planning of appropriate signage to indicate the location of the site and any other relevant information. Advice for workers and students ahead of screening should be considered. An example of messaging for individuals is listed here, together with supporting fact sheets for industry and schools.

Depending on the needs of the local community, signage in alternate languages should also be considered.

Signage should be weatherproof and secured to objects with consideration of work health and safety principles.

Signage and instructions about social distancing, checking in and checking out and mask-wearing can be downloaded from the NSW Health website to assist with consistent messaging.

General and industry specific materials, as well as translated materials are also available.

The Key Questions below should be considered when developing and publishing communication or signage.

- Has the location and hours of the site been communicated to the target audience?
- Do workers and students have access to instructions as to site process?
- Have information brochures for individuals been developed and distributed?
- Has appropriate signage been set up upon entry to the site?

EQUIPMENT, CONSUMABLE AND WASTE MANAGEMENT

Rapid Antigen COVID-19 screening sites and site staff have adequate access to identified resources and re-supply pathways and are aware of escalation pathways.

The officer responsible will need to determine the anticipated demand for stock and the logistics for safe storage and re-supply of both test kits and supporting materials like PPE. Staff working on site should be familiar with the location of stock and stock ordering procedures.

Waste management on site should be considered and planned.

- Used test kits are considered Biohazard Waste and do require special disposal arrangements. For more information on Biohazard go to: https://www.cec.health.nsw.gov.au/keep-patients-safe/COVID-19.
- Used PPE is considered general waste (materials are not recyclable) and do not require special disposal arrangements, however it is recommended that waste be disposed of safely and in

sealed rubbish containers. Regular emptying of rubbish containers should be undertaken to avoid overflow or the need to touch used materials again, once disposed of.

The Key Questions below should be considered when developing plans for equipment and waste management.

- Have supply chains for stock been established and communicated to relevant staff, including escalation pathways for stock shortages?
- Is there an agreed process for removing waste safely from the site?

TESTING SITE OPERATIONS

Registration processes, privacy concerns and traffic movement within the site are clear and effective.

Information should be available to workers and students that use the site to inform them of their privacy and how personal information will be used. There will be reporting of numbers and test results, but all information collected will be de-identified.

Any testing data collected will only be used to help NSW Health make public health decisions. No personal health data is used without consent.

The Key Questions below should be considered when documenting and communicating the operational processes of the site.

- Have flow pathways been clearly mapped out and communicated to staff to ensure there is no congestion in testing sites?
- Is there a one-way flow of traffic so that people do not back-track or pass each other during the process – is this clearly signposted/documented? Sites need to ensure a clear and separated path of travel in and out of waiting areas, including separate exits for people with positive and negative results with consideration for protecting the privacy/confidentiality of a person with a positive test result.
- Have site registration processes (such as QR code check in and check out) been clearly documented and communicated to workers, students and test site staff?
- Have considerations been made as to how site operations should change during periods of surge activity? Have these processes been agreed?
- Are new staff provided with site processes and protocols during orientation?

SUPERVISION OF TESTING AND WORKFORCE

Supervision is a key responsibility for controlling the risks to worker and student safety and welfare that may arise while providing a testing service. Supervision of testing goes to the professional conduct of a practitioner.

Once appropriately trained in the correct use of the device, persons under the supervision of a health practitioner may perform the test. The relevant health practitioner responsible for supervision of testing is required to ensure all persons performing the test (including sample collection, performing tests and interpreting test results) under their supervision are appropriately trained in all matters related to good testing practice, including:

- infection control practices, including assessment of any site-specific work, health and safety risks;
- the collection of samples, or where applicable the supervision of self-collection in order to verify patient identification, sample collection, test performance and test results;
- the correct use of the device and interpretation of test results;
- protocols for recording results and requirements for notification of positive results;
- protocols and referral processes for recollection and confirmatory testing; and
- protocols for reporting any problems or adverse events associated with performance of the test to the Therapeutic Goods Administration.

All health practitioners and persons under their supervision must be trained in the correct use of the device and the interpretation of the test results. A health practitioner remains responsible for the conduct of testing and must be available to provide assistance or advice as required to persons under their supervision in the correct use of the device and the interpretation of the test results.

The ratio of health practitioners to people under their supervision will vary from site to site depending on the size and complexity of the site as well as the experience of the staff in performing the test.

To give guidance to organisations implementing rapid antigen testing, based on advice from industries already using the technology, one health practitioner is required per 40 workers. For example, a site that has 200 workers needing to be screened, may need five (5) health practitioners on site to supervise. This ratio may evolve as the trial sites progress. This advice will be updated regularly based on feedback from the pilot sites to assist other sites with their planning.

An organisation, business or institution that does not have the primary function of providing healthcare services are able to employ or engage a health practitioner as defined by the Therapeutic Goods Administration.

Where samples are self-collected by individuals, the collection must be supervised to verify patient identification, sample collection, test performance and the interpretation of test results.

Definition of a health practitioner (from the Therapeutic Goods Act 1989):

"health practitioner" means a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the following health professions:

(a) Aboriginal and Torres Strait Islander health practice;

(b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist);

(c) medical;

(d) medical radiation practice;

(e) nursing;

(f) midwifery;

(g) occupational therapy;

(h) optometry;

(i) pharmacy;

(j) physiotherapy;

(k) podiatry;

(l) psychology

(m) paramedic

The full definition is available here.

Support Workers

In addition to health practitioners engaged to oversee the testing process, and dependent on numbers of students and workers requiring testing in a period, organisations should consider support services including a concierge function and/or COVID safe marshall for logistics and crowd control; and administration staff to support the process.

MANAGEMENT OF RESULTS

Positive Results

A person who receives a positive rapid antigen test result needs to have an urgent PCR test on a second collection to determine whether COVID-19 is in fact present.

When a person has a positive rapid antigen test result, they must be notified immediately to the NSW Health Public Health Unit (PHU) on 1300 066 055.

The PHU will advise on safe transport to a local COVID-19 testing facility where they will have priority access to a PCR test.

The person with a positive rapid antigen test result must remain in isolation until a definitive result is available. People with a confirmed positive test will have their results reported immediately to the PHU in line with high-risk results procedures.

Negative Results

Continue to follow the latest health advice and restrictions in your area.

If individuals develop any symptoms, even if mild, they must immediately get a standard COVID-19 test and isolate until they get a negative result from NSW Health.

REPORTING OF DATA

As part of the rollout of the trial, NSW Health's Agency for Clinical Innovation will oversee an evaluation of the usage of rapid antigen testing to capture useful insights that will help further enhance the uptake of the technology and measures its effectiveness against stated public health objectives.

Industries and schools who participate in the trial are asked to collect and report basic data in line with the evaluation plan.

In summary, evaluation questions will focus on:

- Is implementation of RAT proceeding successfully?
- How effective is RAT in achieving its objectives?
- What needs to be considered in rolling out RAT more broadly?

Proposed data collection will include:

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

Appendices

A. Testing clinic site checklist

B. Training materials and links

C. Supervisor Competency Assessment Checklist

D. TGA Licensed Rapid Antigen Testing Devices reviewed by NSW Pathology

E. Supporting communications materials

A – Screening site checklist

ITEM	COMPLETED (tick / cross)	DATE
SITE REQUIREMENTS		
Connection to essential utilities		
Clear signage to identify clinic location		
Signage to indicate process / directions to individuals including entry, exit, registration location etc.		
Adequate space for QR code registration space outside or immediately inside building allowing for adequate social distancing		
Adequate space to allow social distancing when lining up prior to receiving test (1.5m between people clearly marked / indicated)		
Adequate space to maintain social distancing in entire area		
Signage to reinforce social distancing requirements		
Wheelchair access – where required		
Accessible toilets with social distancing signage		
Undercover wet weather area (allowing for social distancing)		
One-way flow i.e. one entry and one exit		
Adequate ventilation for enclosed spaces		
SCREENING REQUIREMENTS		
Privacy considerations		
Bench or table for storage		
Garbage bin – secured and emptied regularly		
Adequate numbers of tables and chairs for testing staff (allowing for social distancing)		

PPE REQUIREMENTS		
PPE for workforce (surgical mask, gloves)		
Masks for support staff		
Masks for all individuals awaiting test (to sit at registration tables)		
Signage to reinforce appropriate mask use		
EQUIPMENT & ICT REQUIREMENTS		
Tape to mark social distancing requirements		
Hand sanitiser for registration space and waiting areas		
Information sheets for patients		
Wifi for QR codes and downloading information; Mobile range to make calls to PHU if required for positive test results		
Stationary		
STAFF INSTRUCTIONS		
Staff orientated to site and workflows		
Staff provided with re-stocking of kit supplies process		

B - Training materials and links

A range of training materials have been developed by NSW Health Pathology to support rapid antigen testing in non-clinical settings:

- Handwash Guideline Poster
- Handrub (Sanitiser) Guideline Poster
- Anterior Swab Collection Procedure
- Quality Control Procedure
- RAT Test Procedure and Interpretation of Results

C - Supervisor Competency Assessment Checklist

Element	Operator must understand the rationale and procedural task	Trainee	Supervisor
1. Site preparation	1.1. Prepares necessary equipment and supplies 1.2. Supplies and inventory are adequate for site 1.3. Checks expiry dates of tests and accessories 1.4. Ensures test and supply inventory is managed and records maintained	☐	☐
2. Workplace safety	2.1. Site design is fit for purpose 2.2. Privacy aspects are adequate 2.3. Understands site workflow 2.4. Hand washing / sanitising between clients 2.5. No eating, drinking, smoking permitted on site 2.6. Personal protective equipment 2.7. Workplace (surface and waste) decontamination procedures 2.8. Disinfectant management/preparation procedures 2.9. Accident/incident reporting 2.10. Site emergency procedures (fire, evacuation) 2.11. Waste disposal procedures (for clinical waste)	☐	☐
3. Worker/student consultation	3.1 Welcomes individual 3.2 Introduces self and designation 3.3 Checks correct client information	☐	☐
4. Communication	4.1 Communicates effectively 4.2 Uses pleasant and respectful manner, uses language appropriate to client's level of understanding, uses open body language	☐	☐
5. Professional conduct	5.1 Understands and operates within the professional conduct of the responsible service 5.2 Maintains professional boundaries and does not disclose personal information - maintains client confidentiality 5.3 Maintains a professional and friendly demeanour	☐	☐
6. Immediate management plan – performance of test	6.1 Offers rapid antigen test 6.2 Validates test overall result 6.3 Completes Result Worksheet 6.4 Arranges ongoing management – where applicable	☐	☐

D – TGA Licensed Rapid Antigen Testing Devices reviewed by NSW Pathology

The Therapeutic Goods Administration (TGA) has registered a number of devices for use under the supervision of a health care professional.

Devices that have not been approved by the TGA cannot be used in Australia.

NSW Health Pathology has evaluated several kits that have been approved by the TGA and has set out below a list of products and suppliers for the procurement of test kits.

NSW Health Pathology will continue to evaluate the performance of rapid antigen devices as they become available.

A list of devices for use can be found at the NSW Health website.

E - Supporting communications materials

- FAQ – general
- Information for schools and students
- Information for employers and employees
- Letter for consumers
- Testing brochure – general
- Fact sheet for industry
- Indicative Flowchart Process for Industry