Guidance for the provision of rapid antigen testing for COVID-19 screening in non-clinical settings

(Further guidance will be provided on antigen testing at home as it becomes available in Australia from 1 November 2021)

Dated: 05 October 2021

1. Purpose

This guidance is to support non-clinical settings, including business and industry, who are considering implementing rapid antigen testing as a screening measure in their workplaces.

*High-Risk Industries specified in the Surveillance Industry Testing List must comply with the testing obligations outlined in those requirements before considering this guidance note.*

2. Background

In Australia, reverse transcription polymerase chain reaction (RT-PCR), using a throat and bilateral deep nasal (or nasopharyngeal) swab, is the gold standard diagnostic test for confirming SARS-CoV-2 (the virus that causes COVID-19). It is recommended that anyone with symptoms compatible with COVID-19 be tested using the gold standard method.

In Victoria, turnaround times for PCR testing are usually within 24 to 48 hours. However, in outbreaks or periods of higher community transmission, there is more demand on PCR testing capacity and an alternative testing method may be useful in these circumstances.

The Victorian Department of Health, in collaboration with expert health and pathology practitioners such as the Doherty Institute, have conducted trials of rapid antigen testing, informing this guidance.

Some Australian businesses and industries have commenced using rapid antigen testing and they are used widely internationally, especially where there is higher prevalence and limited PCR capacity.

3. Diagnostic vs Screening tests

Diagnostic and screening tests have different roles.

The purpose of a diagnostic test is to detect the presence or absence of disease in an individual suspected of having the disease.

A PCR test is a diagnostic test, and can confirm if someone has COVID-19, with results available in 24 to 48 hours. These tests generally test a deep nasal sample and throat sample and are tested in laboratories.
A screening test searches for disease in a group of people not necessarily suspected of having the disease. They are used primarily in people without symptoms to determine if an individual has an undetected disease.

Rapid antigen testing is best suited for use as a screening test to help identify a person with covid earlier to help reduce the spread of the virus and prevent outbreaks.

### 4. Rapid antigen tests as a screening tool

Rapid antigen tests are low-cost, can be conducted outside of a laboratory and many provide a result in 15-30 minutes.

However, antigen testing is less sensitive, especially when applied to people without symptoms and so there is a risk of missing cases.

Repeat frequent testing is recommended to offset the reduced sensitivity of antigen testing. The Victorian Department of Health recommends frequency of 3-5 times per week, depending on the accuracy of the chosen test.

Rapid antigen tests can also produce a false positive result, so an incorrect result, especially in low prevalence. Therefore, a positive rapid antigen test does not definitely diagnose a person with COVID-19. Any positive detection on a rapid antigen screening test requires urgent confirmatory PCR testing.

The Victorian Department of Health recommends following the manufacturer’s instructions for the kits purchased, as individual devices may vary.

Any screening program must use the test in accordance with the [National Pathology Accreditation Advisory Council Guidelines for Point of Care Testing](https://www.npatc.asn.au/)

COVIDSafe measures should always be in place, as well as uptake of vaccination even while rapid antigen testing is taking place.

### 5. Appropriate settings for Rapid Antigen testing

Non-clinical settings such as business and industry concerned about COVID-19 exposure may benefit from the use of rapid antigen testing.

Employers should note that where there is little or no community transmission of COVID-19, screening for the virus in low-risk settings (including workplaces) has limited benefit. In these situations, it would be more beneficial for employers to encourage workers to apply COVIDSafe work practices ensure high vaccination coverage, and for employees and their close contacts to get tested and isolate if symptoms develop.

Examples of settings where testing could be used for screening purposes include occupational groups that have the potential for greater exposure to SARS-CoV-2 due to more frequent, close or extended contact with others or in settings where there is a higher risk of workplace transmission of infections.

If a person has any COVID-19 symptoms or is a contact for COVID-19, rapid antigen screening should not be used, and the person should be directed immediately for a PCR test for COVID-19.

### 6. Implementation considerations

The following considerations must be addressed by the health practitioner prior to the implementation of rapid antigen screening:
6.1 Testing program design

The health practitioner in collaboration with the employer will assist with the technical requirements of the program and the design.

Consider the following program design questions:

- Who will be tested and where?
- How often will participants be tested? The Victorian Department of Health recommends frequency is 3-5 times per week, depending on the performance of the chosen test.
- How will testing be conducted? The TGA recommends two ways samples can be collected:
  - Collection by a healthcare practitioner or a trained member of the team
  - Self-collection by an employee under the supervision of a trained member of the team. Self-collection is an acceptable option for a COVID-19 specimen using rapid antigen tests. However, poor specimen quality is a common concern and can result in false results, as well as the misidentification of specimens. Self-collection must be supervised by a trained member of the collection team, preferably in person and onsite, however, remote supervision of sample collection can also be explored as stated in the Conditions of supply for rapid antigen tests-TGA
- How will testing be managed for employees that are on leave or off shift?
- What communication and processes are needed for standing up and standing down the workplace testing program?
- Will the testing program will be voluntary or mandatory?
- How will you register and record participant details and results? (e.g. online registration form accessed via QR code)

6.2 Selection of antigen test

Only approved rapid antigen tests registered with the Therapeutic Goods Administration can be used for COVID-19 testing. Rapid antigen tests must be used in accordance with their specific ‘Instructions for Use (IFU).’

Selection of the rapid antigen test should consider the performance metrics of the individual test. A March 2021 review of evidence assessed the accuracy of antigen tests in people with symptoms and people without symptoms.

There is limited Australian peer reviewed data, except Multi-site assessment of rapid, point of care antigen testing for the diagnosis of SARS-CoV-2 infection in a low prevalence setting: A validation and implementation study

The supply of rapid antigen tests for self-testing of COVID-19 (without the direct supervision of a healthcare professional), is prohibited under the Therapeutic Goods (Medical Devices - Excluded Purposes) Specification 2020.

The TGA notes:
There must be a designated health practitioner (as defined in the Therapeutic Goods Act 1989, Chapter 1, 3(1) or paramedic who will be the PoCT supervisor This health practitioner will take responsibility and accountability for the conduct, quality and implementation of the testing being performed and must be trained by the supplier in the use of the rapid antigen test.

Businesses or industries wishing to implement rapid antigen testing of their workers should refer to the TGA website that provides further information on what processes and protocols you need to have in place to safely conduct testing. This includes protocols for training of staff and assessing ongoing competency. It is not sufficient to rely on the initial training provided by the supplier of the test.
For further information on conditions of supply for rapid antigen tests through the TGA contact COVIDtests@tga.gov.au or telephone 1800 141 144.

6.3 Testing program costs
Rapid antigen COVID-19 testing is not covered under the Commonwealth’s Medicare Benefits Scheme.

Rapid antigen tests vary in cost but are usually between $10-$20 per unit. Additional implementation costs, including supervising workforce, personal protective equipment (PPE), waste management and results management also need to be considered. Supply chains, ordering processes, shelf life of products, storage facilities and logistics must be established to ensure the ability to provide ongoing provision for rapid antigen testing onsite.

Testing program costs are the responsibility of the business/industry unless otherwise stated by the Department.

6.4 Locating and setting up a testing site
Refer to Appendix 1 - TGA Checklist when considering rapid antigen testing

Refer to Appendix 2 – Setting up a testing area

6.5 Management and operations of testing
Ongoing management of the screening site is the responsibility of the health practitioner engaged or employed by the employer.

The employer and health practitioner must ensure a process of screening of the trained workforce team including assessing for any symptoms or visiting of any exposure sites. In either occurrence, the trained workforce team should be directed to immediate PCR testing and isolate according to relevant public health advice.

The health practitioner, medical practitioner or paramedic remains responsible for the conduct of testing. The training and operational responsibilities of the practitioner are outlined in Conditions of supply for rapid antigen tests on the TGA website. Below are some examples:

- Communication to workers about the testing process
- Management of the testing process and safety of the site for workers under their guidance
- Ensuring correct rostering of trained workforce members to ensure there is minimal wait times for checking in and waiting for results
- Ensuring there is correct and adequate PPE including surgical masks, gloves, gowns, eye protection (goggles or face shields). Every sample must be considered infectious
- PPE donning and doffing stations placed at transition from each zone
- Ensuring staff are practicing good hand hygiene between each test
- Adequate hand sanitiser available for use
- Cleaning and disinfecting surface between tests to prevent contamination of samples
- Cleaning schedules in place for routine cleaning and additional COVID-19 cleaning for communal spaces for high touch surfaces to be cleaned and disinfected twice daily.
- A safe registration process for checking in and checking out. For example, QR code or manual records
- Clinical waste management and correct disposal
Registration process may differ from employer to employer. It is essential that all sites ensure:

- Privacy is always maintained, including their personal information. Test numbers will be reported to the Department of Health. No personal data will be used without the consent of the employee.
- Traffic management is deployed within the site depending on the size of the site and the number of employees being tested.
- Employee flow pathways are established for testing depending on the location chosen. This is to ensure there is no back-tracking of employees throughout the testing process.
- Registration processes are clear to all participants undertaking testing.
- Considerations for increased capacity should be considered for times of high demand.

Adequate equipment, consumables and waste management at the site are required, including:

- Protective Personal Equipment: PPE is NOT recyclable and is considered clinical waste and would need to comply with EPA guidelines.
- Rapid antigen testing kits.
- Supply chains and ordering processes must be in place.
- Storage of excess stock, in line with the conditions recommended by the manufacturer.
- Used rapid antigen kits are considered a biohazard waste and must be disposed of in line with the EPA Guidelines.
- All waste must be removed safely and regularly from the site.

6.6 Signage and Communications

Signage for physical distancing, mask wearing, hand hygiene, clinical waste management and registration process for checking in and results managements must be displayed.

All outdoor signage must be weatherproof and secured in line with workplace health and safety principles.

General signage at the entrance must clearly state:

- Rapid antigen screening for COVID-19 site
- Operational hours of the site opened
- Instructions while onsite

Department of Health signage to support implementation at your screening site:

- Physical distancing
- Face masks for your business
- Victorian QR code app for registration purposes
- Multilingual business posters

6.7 Supervision of testing, training, and workforce

All staff members who will perform testing need to be trained in the correct use of the rapid antigen testing device (including specimen collection) and interpretation of results. This training needs to be undertaken prior to commencement of any testing.
As a minimum, the supplier of the test needs to provide training to the health practitioner and the staff performing or overseeing testing. Once trained, a health practitioner can train persons under their supervision to conduct the test.

Health Practitioner as defined by the Therapeutic Goods Act 1989 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

Paramedics are not included in the definition of Health Practitioner in the Act but have been specified as a suitable health practitioner for the purposes of supply and use of rapid antigen tests. A health practitioner, including a medical practitioner or paramedic, who performs or supervises rapid antigen testing, takes on full responsibility for all testing conducted under their supervision including keeping records of such training.

Suppliers (sponsors) will need to have procedures in place for performing training, and a means of assessing and recording the competency of the person being trained. Certification for such training is not necessary.

Health practitioners should be provided with a checklist for training staff under their supervision by suppliers.

Use of the test by untrained persons and testing performed outside the supervision of a health practitioner is prohibited.

The TGA indicates that the health practitioner responsible for testing must ensure all staff members are trained in (but not limited to):

- 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 people with a positive antigen test for covid
- protocols and referral processes for recollection and confirmatory testing
- protocols for reporting any problems or adverse events associated with performance of the test, including issues with labelling or packaging to the Therapeutic Goods Administration.

A video has been developed using the Abbott PanBio antigen test, however, include relevant information that can be applied to other antigen tests. A booklet supporting the video can be used as a quick reference.

6.8 Management of Results
The health practitioner, medical practitioner or paramedic performing or supervising performance of the test is responsible for ensuring protocols are in place for notifying positive results as per the national guidelines developed by the Communicable Disease Networks Australia (CDNA). These are the minimum standards for surveillance, laboratory testing and contact management for COVID-19.

Note: An antigen test which shows 2 visible lines after waiting the required time for a result is considered a positive antigen result for COVID-19. This means the person may have COVID-19 and MUST present to a testing site for a PCR test to confirm whether the antigen test is correct. This will be guided by the health practitioner overseeing the testing program.

Appendix 3 outlines the Management of results for rapid antigen testing - nonclinical settings under a health practitioner supervision

The TGA states “It is not acceptable practice to just repeat the rapid antigen test in the hope of the second test being negative. Any positive result needs follow up with a PCR test.”

All positive rapid antigen tests must be immediately notified to the health practitioner overseeing the testing framework within the organisation or company.

A PCR (Priority 1) test must then be ordered by the health practitioner. Pathology request forms for a PCR test must state the reason for the request was a positive rapid antigen test result.

The health practitioner must immediately notify the Department of Health (so they are aware of the antigen result and pending confirmatory PCR). See Reporting Management of positive antigen result to Department of Health

Appendix 4 demonstrates the flowchart of rapid antigen test-based surveillance testing protocol incorporating testing 3-5 times per week and results management.

All people who receive a positive rapid antigen test result must wear a mask, isolate and await direction from the supervising health practitioner. If possible, they should attend the testing clinic closest to their home for a PCR test and avoid using public transport, taxis or rideshare. After their PCR test, they must isolate until the result is known. Taking the test | Coronavirus Victoria will assist employees to understand what a PCR test entails.

Victorian workers can apply for a COVID-19 Test Isolation Payment that provides financial support while they or someone they are caring for self-isolate while awaiting the result of a COVID-19 test.

There are a variety of financial support packages for people and businesses impacted by COVID-19, including financial, job and business support.

If a positive rapid antigen test has been confirmed by a positive PCR test, the worker will be advised by the health practitioner and will be contacted by the Department of Health or Local Public Health Unit.

Advice on what to do if you test positive for coronavirus can be found here.

6.9 Reporting management of positive antigen result to Department of Health

The health practitioner must immediately notify the Department of Health by filling out this form, so they are aware to match a positive rapid antigen test to a pending PCR result.

Data points required for the notification:

<table>
<thead>
<tr>
<th>Collection data</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location site</td>
<td></td>
</tr>
<tr>
<td>Location health practitioner lead</td>
<td></td>
</tr>
</tbody>
</table>
6.10 Program evaluation and data reporting

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

The Department of Health Victoria requests businesses/industries collect and retain the following data throughout the testing program to enable evaluation of the surveillance program.

- Type of rapid antigen test product used
- Total number of tests conducted
- Negative results for COVID-19
- Positive results and subsequent action (notify the Department of Health)
- False positive results (results that were positive on the antigen test but negative when a PCR was conducted)

7. Resources

Antigen factsheet for Employers
Antigen factsheet for Employees
Video to support workflow on site - Australian Prostate Centre

Covid-19 Rapid antigen Point of Care Testing – Guidance for implementation and Checklists for Business - Therapeutic Goods Administration
Swab collection and interpretation of results refer to the ‘Instructions for Use’ – Therapeutic Goods Agency
Occupational Health and safety Act and Regulations 2004 - Worksafe
Signs, posters, and templates for your workplace - Department of Health
Case and Contact management guidelines - Victorian State Government Health and Human Services

Infection prevention and control
Reduce the risk of COVID-19 exposure and infection resources - The Australian Commission on Safety and Quality and Health Care
Infection Prevention and Control resources – Department of Health
Preventing infection in the workplace – Victorian Government
Disposing of clinical waste – Environment Protection Authority of Victoria
Appendices

Appendix 1 - TGA Checklist when considering Rapid Antigen Testing

It is recommended that businesses implementing Rapid Antigen Testing take into consideration the following:

- An appropriate rapid antigen test registered in the Australian Register of Therapeutic Goods (ARTG) is sourced for use considering sample type, clinical sensitivity, clinical specificity, storage requirements of test kits and samples.

- There are appropriately trained medical Professionals or health professionals available who will be the PoCT supervisor(s). These health professionals will take responsibility and accountability for the conduct, quality, and implementation of the testing.

- All health professionals, and staff performing testing under their supervision, are trained in the safe and correct performance of the test, including sample collection.

- Suppliers of tests must provide training to health professionals. Business will need to supplement this and put in place additional training protocols for training of staff that will operate under the supervision of the health professionals. Protocols will need to include ongoing training and competency checks and take into consideration the business's existing COVIDSafe plan, standard operating procedures, and other arrangements.

- Procedures are in place for ensuring any associated equipment and instrumentation is maintained according to manufacturer's instructions and appropriate records are kept.

- There are protocols for recording all relevant information such as staff training; performance of testing (e.g. when performed, who by and on whom), test results.

- Protocols are in place for when a positive result is received including procedures for recording results and requirements for notification of positive results to State and Territory organisations (for follow up laboratory PCR testing and contact tracing), to individuals and what this means for the workplace.

- Procedures are in place for privacy and confidentiality of individuals with appropriate consents.

- The Rapid Antigen Testing site is in a safe and easily accessible place which includes adequate access to essential services (e.g., power, water), QR check in code for the site, is well lit, secure, offers appropriate weather protection and suitable for COVID safe spacing and flow with adequate PPE, masks, and hand sanitising stations.

- 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.

- There are appropriate infection control practices and Work Health, and Safety (WH&S) protocols are in place.

- There are protocols for reporting any problems or adverse events associated with performance of the test, including false negative or false positive results, to the Therapeutic Goods Administration (TGA).

Please note: this is not an exhaustive list and should be considered in conjunction with National and State Legislation.
## Appendix 2 - Setting up testing area

<table>
<thead>
<tr>
<th>ITEM</th>
<th>Completed</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SITE REQUIREMENTS - location within a workplace</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Connection to essential utilities (landline telephone or mobile with cellular reception for calls to Department of Health for reporting of positive test results)</td>
<td></td>
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</tr>
<tr>
<td>Clear signage to identify clinic or testing location</td>
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</tr>
<tr>
<td>Signage to indicate process / directions including entry, exit, registration location</td>
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<tr>
<td>Adequate space for registration process of employees</td>
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<tr>
<td>Site choice must ensure adequate space to maintain physical distancing</td>
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<tr>
<td>Marked spaces to allow physical distancing when lining up prior to testing</td>
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<tr>
<td>Signage to reinforce physical distancing requirements</td>
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<tr>
<td>Accessibility for all workers</td>
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<tr>
<td>Undercover wet weather area (allowing for social distancing)</td>
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<tr>
<td>Ability to create one-way flow of employees for testing, i.e., one entry and one exit</td>
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<tr>
<td>Adequate ventilation for enclosed spaces. Ventilation sources (for example, open windows, doors or heating, ventilation and air conditioning systems) should be available to supply fresh air to the space.</td>
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<tr>
<td>Cleaning and disinfection products (for example, 2-in-1 cleaning and disinfection wipes) to be used on frequently touched surfaces.</td>
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<tr>
<td>An isolation area for a worker who receives a positive rapid antigen test where they can isolate safely and await further instructions. Appendix 3 - Management of positive result</td>
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<td></td>
</tr>
<tr>
<td>PPE donning and doffing stations</td>
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<tr>
<td><strong>SCREENING REQUIREMENTS: workflow within a site</strong></td>
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<tr>
<td>Privacy considerations for personal information discussion, space for testing, result management conversation</td>
<td></td>
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</tr>
<tr>
<td>Placement of tables and chairs for one-way workflow and physical distancing</td>
<td></td>
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<tr>
<td>Placement of waste management equipment in line with workflow</td>
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<tr>
<td><strong>PPE REQUIREMENTS</strong></td>
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<tr>
<td>Tier 2 PPE (surgical mask, disposable gloves, level 1-4 gown, eye protection either goggles or face shield)</td>
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<tr>
<td>Single-use surgical masks for administration staff</td>
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<tr>
<td>Single-use surgical masks for all individuals awaiting test (to sit at registration tables)</td>
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</tr>
<tr>
<td>Signage to reinforce appropriate mask use, PPE donning and doffing, and good hand hygiene</td>
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</tr>
<tr>
<td><strong>EQUIPMENT AND TECHNOLOGY REQUIREMENTS</strong></td>
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<td></td>
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<tr>
<td>Tape to mark physical distancing requirements</td>
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<tr>
<td>Hand sanitiser for registration space, waiting areas and testing areas</td>
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<td>----------------------------------------------------------------------</td>
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<tr>
<td>Bench tops, tables for storage, chairs, bins (refer to <a href="#">EPA guidelines</a> for disposal of clinical waste)</td>
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<tr>
<td>Information sheets for patients and WiFi for QR codes for downloading information;</td>
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<tr>
<td>Non-touch administration processes are preferable for infection control purposes over using manual check in using pen and paper for stationary</td>
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</tr>
<tr>
<td>Stopwatch to ensure the result is read in accordance with the manufacturer’s Instructions for Use to ensure accurate results</td>
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<tr>
<td>Technology includes a secure computer, tablet, software to record results and capture data required by Department of Health</td>
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<tr>
<td><strong>STAFF INSTRUCTIONS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff orientated to site and workflows</td>
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</tbody>
</table>
Appendix 3 - Management of results

Management of results for Rapid Antigen Testing – non-clinical settings under health practitioner supervision

IMPORTANT:
Please follow your local protocol to undertake a PCR test if you have symptoms: fever, sore throat, cough, shortness of breath, runny nose, loss of taste, loss of smell

NEGATIVE result process:
1. Worker notified of negative test via their local protocol for result’s management.
2. Worker to proceed to workplace.

POSITIVE result process:
1. Notify health practitioner in charge of testing program immediately.
2. Worker notified of positive test via their local protocol for result’s management.
3. Health practitioner to notify Dept Health immediately.
4. Health practitioner to order PCR test in line with Dept Health advice.
5. Worker must wear a mask, isolate, and follow the direction of the health practitioner waiting for a PCR result.

Top Tips:
- ALL SYMPTOMATIC workers MUST have a PCR test.
- ALL positive rapid antigen tests MUST be reported to Dept Health immediately.
- ALL workers with a positive rapid antigen test MUST have a PCR test to confirm.
- ALL workers with a positive rapid antigen test MUST wear a mask, isolate and follow the direction of the health practitioner while waiting for a PCR result.

Pre-test requirements:
- Workers must register for testing and follow their local protocol for onsite rapid antigen testing.
- Workers must physically distance and wear masks while waiting for testing.

Post-test requirements:
- Results may be delivered in 20 mins following the test. ALL results must be recorded in a records management system regardless of result.
Appendix 4 – Flowchart of rapid antigen surveillance testing protocol

Minimum 3-5 times per week RAT. All on-site workers

Positive RAT result

Negative RAT result

Test result escalated to lead health professional. Report result and follow up PCR (Priority 1)
(Wear mask and isolate)

Positive PCR result

Confirmed COVID-19 case

OFFICIAL