



Australian Government
Department of Health
Therapeutic Goods Administration

COVID -19 Rapid Antigen Point of Care Testing

Guidance for implementation and checklist for businesses

Version 1.1, 7 September 2021

TGA Health Safety
Regulation

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Introduction

The purpose of this document is to provide some guidance to businesses who are considering using COVID-19 rapid antigen tests to ensure they understand the key considerations when performing rapid antigen point of care tests (PoCTs).

It should be noted that this document is an interim document as further, more detailed guidance on undertaking COVID-19 testing for workplace screening is being developed by the Department of Health.

Background

Over the last few months there has been expansion of rapid antigen testing for use in both health and non-health sectors. However, even with the current COVID outbreaks in Australia, compared with many other countries the prevalence of the disease is low in Australia. In this low prevalence environment, the lower sensitivity and less than 100% specificity of rapid antigen tests will result in some false negative and some false positive results.

The Therapeutic Goods Administration (TGA) has approved a number of rapid antigen tests for supply in Australia. So that they are appropriately used, and the results interpreted correctly, they can currently only be legally supplied under specific conditions. These include for use by specified trained health practitioners and trained staff under their supervision to ensure a suitable health practitioner is available to provide immediate clinical advice and treatment if required. The conditions were recently updated to clarify:

- in what circumstances the tests can be supplied
- who can perform the test; and
- the requirements for supervision of testing.

These conditions reflect the importance of correct interpretation of results, advice and treatment being available at the time of testing. The requirement for health care practitioner involvement and the prohibition on self-testing (home testing) reflect the critical importance of immediate notification of positive cases to state and territory health authorities so that contact tracing and processes to manage outbreaks can immediately start.

In a potential later scenario, where low level community transmission is being tolerated in a vaccinated population, it may be appropriate to review these requirements. Planning for the greater use of rapid antigen testing as part of Australia's COVID-19 testing strategy in the future is underway.

This information should be read in conjunction with all relevant national and jurisdictional legislation and the conditions the TGA has placed on supply of these tests. Information on the conditions of inclusion is available on the [TGA website](#) with further explanation provided through questions and answers [here](#).

General Considerations

1. 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.

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.

For the purpose of rapid antigen testing health practitioner also includes a person registered under a law of a state or territory to practice paramedicine.

2. There must be protocols in place to manage safety of both the persons performing the test and the persons being tested.
 - a. This includes having adequate infection control protocols in place to ensure the safety of staff and persons and to prevent the spread of infection.
 - b. There must be protocols relating to Workplace Health and Safety (WH&S) that are consistent with relevant national and jurisdictional workplace health and safety requirements.
 - c. Every sample may be infectious and staff performing the tests should wear appropriate Personal Protective Equipment (PPE) (e.g. gloves, mask, gown, eye protection).
 - d. Any accidents or incidents must be reported to the PoCT supervisor and followed up according to local workplace requirements.
3. The designated health practitioner must be clearly identifiable and accessible and have the competence to ensure and take responsibility for all testing being performed (including staff training) and be available to provide clinical advice when required.
4. The health practitioner must ensure that staff performing or supervising the performance of the test are trained in the correct performance and interpretation of the test including specimen collection.

Note: inadequate sample collection can affect the accuracy of the test.
5. The privacy and confidentiality of individuals must be maintained at all times. Consent should be obtained from the individual to allow the collection and testing to be carried out.
6. Collection of specimens must be performed with accurate identification of the person being tested to ensure traceability of specimen collection to final result.
7. If self-collection of a swab is necessary this must be conducted under the supervision of a person who has been trained in sample collection in order to verify patient identification

and ensure an appropriate sample is collected. Poor sample collection can result in false negative results.

8. There may be circumstances where it is necessary for certain essential workers (such as disability or aged care home care workers) to have the test performed off-site under remote supervision. In this situation the business or organisation need to establish protocols to allow for remote supervision of testing under strict criteria, see further information under heading of 'Remote Supervision'.
9. Any state and territory requirements for COVID-19 testing of workers must be taken into consideration.

Test choice consideration

10. A list of all rapid antigen tests approved for supply in Australia is available on the [TGA website](#) and is regularly updated as new tests are approved or if tests are cancelled or withdrawn.
11. The instructions for use provide with the rapid antigen tests will provide information on the performance characteristics of the test such as sensitivity, specificity and storage requirements. The following should be considered when selecting a rapid antigen test to use:
 - Sample type (e.g. nasal, nasopharyngeal swab, saliva) – what sample types do you want to collect and what does it say in the instructions for use that the test can be used with.
 - Clinical sensitivity (higher sensitivity will reduce the number of false negatives).
 - Clinical specificity (higher specificity will reduce the number of false positives).
 - Storage requirements of the test kits (can the test be stored at room temperature prior to use or does it require other storage arrangements).
 - Storage requirements of samples once collected (how long can the sample be stored and at what temperature).
 - Collection and storage of samples must be performed in accordance with the manufacturer's instructions. This may be a consideration for follow-up laboratory confirmatory testing.

Test Performance

Factors such as sample collection and sample application can all affect the quality of the results obtained.

12. Protocols are required for:
 - infection control practices
 - identification of the person being tested
 - correct sample collection technique
 - correct sample preparation and performance of the test (manufacturer's instructions for performance of the test must be followed)

- reagents and consumables must be stored in accordance with the manufacturer's instructions.
 - correct interpretation of the test
 - recording of test results
 - obtaining timely clinical advice if required
 - management of positive results and arrangements for confirmatory tests
 - notifications of positive results to public health authorities.
 - for safe disposal of samples and used tests
 - performing and monitoring quality control to ensure tests are working correctly.
 - for reporting adverse event or problems with the test to the Therapeutic Goods Administration.
13. Manufacturer's instructions for the maintenance of instruments and associated equipment must be followed.

Training

So that they are appropriately used, and the results interpreted correctly, health practitioners and all staff performing the test must be trained in the correct use and interpretation of the test, including specimen collection. Adequate numbers of health practitioners and trained staff need to be available for the number of employees to be screened.

14. Suppliers as a minimum need to provide training to the health practitioners performing or overseeing performance of the test. Suppliers will need to have procedures in place for performing training (including mentorship programs) and a means of assessing and recording competency of a person. Suppliers should also provide health practitioners with a training competency checklist so they can provide training to staff under their supervision.
15. Testing must only be performed by trained health practitioners, or trained persons operating under the oversight of the health practitioner.
16. Records of staff training must be kept.
17. Training should include but not be limited to the following areas:
- a. sample collection
 - b. procedures for the safe performance of tests and accurate interpretation of results
 - c. confidentiality of patient and client information
 - d. workplace health and safety and infection control protocols
 - e. information on administering a test and delivering a test result
18. Training protocols also need to take into consideration the business's existing COVID safe plan, standard operating procedures, and other arrangements.

Remote Supervision

19. The conditions allow for rapid antigen tests to be supplied to business or organisations that employ or engage relevant health practitioners to perform or oversee performance of testing on their staff or students of the organisation, business or institution. Preferably such testing would be performed on-site under the supervision of a trained health practitioner, or trained person operating under their oversight. Where employees are distributed across multiple geographical locations businesses or organisation may need to consider establishing 'testing hubs' to facilitate supervised testing.

However, there may be circumstances where it is necessary for certain essential workers (such disability or aged care home care workers) to have the test performed off-site under remote supervision. In this situation the business or organisation could establish protocols to allow for remote supervision of testing under strict criteria outlined below.

A business or organisation would need employees to be trained in how to self-collect a sample and perform and interpret the test. Once this was completed the employee could be provided with a number of tests they could use off-site under remote supervision.

To ensure compliance with the conditions of supply and use of rapid antigen tests the site collection centre would need to:

- Record how many tests were supplied to the employee
- Identify who would be responsible for the remote supervision arrangements for that employee
- Have protocols in place to facilitate remote supervision of testing
- Have protocols in place for recording when testing is performed, by whom and who the supervising health practitioner (or trained person under their supervision) was.
- Ensure availability of a health practitioner, or trained person under their supervision, at the time the employee needs to perform the test.

The health practitioner, or trained person under their supervision, would need to ensure:

- Training is provided to each person on how to self-collect a sample and how to perform the test as per the instructions for use.
- A copy of the instructions for use for the test is provided to the employee. This is particularly important as the tests come in boxes of 20 or more with only one copy of the instructions for use. All employees being provided the test need to have access to a copy of the instructions for use that is in the preferred language of the employee.
- The employee is provided with instructions for how to access remote supervision (e.g. via mobile phone) and record and report results.

Other Considerations

20. That COVID-19 screening sites are located in a safe and easily accessible site which includes adequate access to essential services (e.g. power, water), QR check in code for the site, well lit, secure, offers appropriate weather protection and suitable for COVID safe spacing and flow with adequate PPE, masks and hand sanitizing stations.

21. That there is adequate signage and instructions and appropriate biological waste management and disposal processes in place.

Checklist for business 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 giving consideration to sample type, clinical sensitivity, clinical specificity, storage requirements of test kits and samples.
- There are appropriately trained medical Practitioners or health practitioners available who will be the designated PoCT supervisor(s). These health practitioners will take responsibility and accountability for the conduct, quality and implementation of the testing.
- All health practitioners, and staff performing testing, are trained in the safe and correct performance of the test, including sample collection.
- Suppliers of tests must provide training to health practitioners. Business will need to supplement this and put in place additional training protocols for training of staff that will operate under the oversight of the health practitioners. Protocols will need to include on-going training and competency checks and take into consideration the business's existing COVID safe 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 work place.
- Procedures are in place for privacy and confidentiality of individuals with appropriate consents.
- The rapid antigen testing site is located 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 sanitizing 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/Territory Legislation.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration	August 2021
V1.1	Update to 'Remote Supervision' and other minor amendments,	Therapeutic Goods Administration	September 2021

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

Reference/Publication #