



Australian Government

Department of Health

Therapeutic Goods Administration

COVID -19 Rapid Antigen Point of Care Testing

Guidance for implementation and checklist for businesses

Version 2.0, January 2022

TGA Health Safety
Regulation

Copyright

© Commonwealth of Australia 2022

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Introduction	4
Background	4
General considerations	4
Test choice consideration	6
Test performance	6
Training	7
Remote supervision	7
Other considerations	8
Checklist for business when considering rapid antigen testing	9

Introduction

The purpose of this document is to provide some guidance to businesses who are considering, or are, using COVID-19 rapid antigen tests that are approved by the Therapeutic Goods Administration (TGA) as point-of-care test for use by trained health practitioners and trained staff under their supervision. A business can choose instead to use rapid antigen tests that are approved by the TGA for use as self-tests. In this case the involvement of a health practitioner is not required although this guidance still provides relevant information on how a business can safely implement testing in the workplace.

Background

The Therapeutic Goods Administration (TGA) has approved a number of rapid antigen point-of-care 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 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.

Business can purchase rapid antigen point-of-care tests to test their employees but only if they engage or employ a health practitioner or paramedic who will be responsible for performing the test or supervising the performance of the test by trained staff. Smaller businesses may only need a health practitioner to be available for short periods of time by the phone or by videoconference to assist or advise as required,

A health practitioner may also screen patients under their direct care for COVID-19 but there is no requirement that they must do this. Except for pharmacists, healthcare practitioners are not permitted to provide a general testing service for members of the public.

This information should be read in conjunction with all relevant national and jurisdictional legislation. There is additional information on the TGA website about [COVID-19 rapid antigen point-of-care tests](#) and conditions of their supply, with further explanation provided through [questions and answers](#).

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 point-of-care tests, 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 or incorrect 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 [‘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 point-of-care tests approved for supply in Australia is available on the [COVID-19 test kit](#) page 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 point-of-care 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
 - where applicable, recording of test results

- obtaining timely clinical advice if required
- management of a person with a positive result including provision of information on how they can report a positive results according to the local health authority requirements.

As different states and territories may have different recommendations for testing and for reporting positive results please see their website for any local requirements.

- 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.
- The employee is provided with advice on any [state and territory requirements](#) for reporting a positive test result to their state or territory health department.

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 any necessary 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 (if required), 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
V2.0	Addition of 'Testing of general public carried out in a pharmacy' and update to confirmatory testing and reporting requirements.	Therapeutic Goods Administration	January 2022

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 #