Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Q&As on conditions of supply for rapid antigen point of care COVID-19 tests

Guidance

Answers to frequently asked questions in relation to rapid antigen tests.

Last updated: 16 May 2024

These questions and answers are for COVID-19 rapid antigen point of care (POC) tests.

If you would like information on the COVID-19 rapid antigen self-tests (home use tests) tests go to COVID-19 rapid antigen self-tests.

Open all | Close all

What is the difference between COVID-19 rapid antigen point of care and self-tests?

Point of Care rapid antigen tests are designed for larger-scale professional testing and require user training. So that point of care tests are appropriately used, and the results interpreted correctly, they can only be legally supplied under specific conditions for use by trained health practitioners, and trained staff under their supervision. They are general packaged in much larger numbers of

individual tests as self-tests.

They are not the same as COVID-19 self-tests (home use tests) which contain individually packaged tests and which have been assessed by the TGA for usability by untrained members of the public. For self-tests it is also required that phone support for members of the public is available from suppliers of the tests.

Where do I find out what tests are approved and who can supply these tests in Australia?

A list of all rapid antigen tests (both Point of Care and Self-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is available on the TGA website and is regularly updated as new tests are approved or if tests are cancelled or withdrawn.

You will need to contact the suppliers (sponsors) directly for further information on availability and cost of particular rapid antigen tests.

Where do I purchase the tests from, how much do the tests cost and how often do I need to test and what are the requirements in my state/territory/local area?

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is available on the TGA website and is regularly updated as new tests are approved or if tests are cancelled or withdrawn.

You will need to contact the suppliers (sponsors) directly for information on a how much the tests cost and how to purchase a rapid antigen test.

Different state and territory jurisdictions may have differing testing requirements for essential workers, based on their public health orders. The responsibility for reporting positive test results to state and territory health departments typically rests with the individual being tested. Contact the relevant state or territory government or see their websites for more information on whether reporting of positive test results is required and how to report a positive result.

Point of Care rapid antigen tests are not permitted to be sold to individuals for self-testing at home; only TGA-approved Self-Tests should be supplied and used for this purpose. See question on *Where or who can the tests be supplied to?* for further information.

Are Medicare benefits payable for the supply of a COVID-19 rapid antigen point-of-care test?

No. Medicare does not cover COVID-19 rapid antigen point-of-care tests. Medicare also does not fund COVID-19 screening.

What does an individual need to do if they test positive for COVID-19?

If you are told you have a positive test result you will need to check what you need to do next according to the directions of your local health authorities.

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

- whether confirmatory PCR testing is required;
- any specific health advice including isolation requirements; and
- whether the result is required to be reported to your state or territory health department or other government agency.

Why has the TGA imposed conditions on supply for point of care rapid antigen tests?

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 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 updated in January 2022 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.

Where it is not possible for a health practitioner to be physically present at the point of care the trained staff member may be someone who is not a health practitioner but could for example be the proprietor or a staff member of a small-medium business. Small businesses only need to have a health professional such as a nurse or pharmacist to be available on the phone or by videoconference to provide assistance or advice, as required, to persons under their supervision. For a small business, this may only need access to a couple of hours of a health practitioner's time (e.g. a pharmacist or nurse).

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.

Can tests be performed by persons who are not health practitioners?

Yes, but the testing needs to be performed under the overall supervision of a health practitioner, medical practitioner or paramedic and the person performing the test needs to be trained in the correct use and interpretation of the tests. Where it is not possible for a health practitioner to be physically present, the supervision does not need to be direct. See question, *Does the Health Practitioner need to be on-site?*

Use of a point of care test by untrained persons and testing performed outside the supervision of a health practitioner would mean that the person or organisation could be liable if something goes wrong with the performance or interpretation of the test.

For information on relevant health practitioner see the question, *What is meant by health practitioner?*

Where or who can the tests be supplied to?

The tests can be supplied to the following:

a. Health practitioners, medical practitioners or paramedics to perform or oversee performance of the test on their staff or patients under their direct care. "Health Practitioner" is defined by the *Therapeutic Goods Act 1989* and 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
b. Pharmacists to perform or oversee the performance of the test on their staff or to provide a screening service for members of the general public. See question, *Can tests for the general public be carried out in a pharmacy?*

c. Residential care (disability and rehabilitation facilities) and aged care facilities that employ or engage health practitioners (for example, nurses) to conduct or perform the test. If the residential care or aged care facilities provide care in the home this condition would also allow for performance of the test to be conducted by a health practitioner or paramedic. The tests can only be used to test residents, staff of, or visitors to, the residential care or aged care facility, or clients and staff of the home care service provider.

d. Organisations, businesses, or institutions that employ or engage health practitioners or paramedics to conduct or oversee performance of the tests on their staff or students. For example, rapid antigen tests are being used in the mining sector consistent with these conditions.

The tests can also be supplied to accredited laboratories and to Commonwealth, state or territory government departments in cooperation with their relevant health departments.

Can tests for the general public be carried out in a pharmacy?

Pharmacies, if they choose to do so, can perform tests for screening of the general public. While a registered pharmacist does not have to perform the test personally, they must oversee the performance of the test and the tests have to be performed at the premises of the pharmacy. The point of care tests themselves cannot be provided by pharmacies for retail sale.

Note that it is strongly advised that symptomatic or potentially infected individuals do not visit local community pharmacies to be tested, due to the risk of infection of pharmacy staff and other customers. In contrast, at dedicated COVID-19 testing centres, strict mask and sanitisation protocols are required for those being tested, and staff at the centre wear full personal protective equipment at all times.

It is important that any community pharmacy considering offering a rapid antigen point of care testing to the general public takes into consideration the implications of testing in these environments, including:

- processes to maintain confidentiality of personal information
- any state and territory directions around rapid antigen testing including reminding individuals who test positive that they may be legally required to report a positive test result to their state or territory health department

Any fee for providing such a service would be at the discretion of the pharmacy.

What is meant by health practitioner? Is this the same as a healthcare professional?

Health practitioner is defined in Section 3 of the *Therapeutic Goods Act 1989* (the Act) and is not necessarily the same as a healthcare professional. The conditions of inclusion on rapid antigen tests refer specifically to a health practitioner and not 'healthcare professional'.

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:

- Aboriginal and Torres Strait Islander health practice
- dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist)
- medical
- medical radiation practice
- nursing
- midwifery
- occupational therapy
- optometry

- pharmacy
- physiotherapy
- podiatry
- psychology

The list above includes medical practitioners, pharmacists, and nurses along with others, but not for example pharmacy assistants, dental assistants, or personal care workers in aged care. 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.

The registration or licensing of a health practitioner, can be checked through the Australian Health Practitioner Agency (AHPRA). For the purposes of rapid antigen testing health practitioner also includes a person registered under a law of a state or territory to practice paramedicine (as specified in the conditions of inclusion).

A health practitioner, including a 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. For further information see question *What are the responsibilities of the health practitioner?*

Who requires training?

Everyone who will perform the test needs to be trained in the correct use of the 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 practitioners or paramedics performing or overseeing testing. Once trained, a health practitioner or paramedic can train persons under their supervision to conduct the test.

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.

Suppliers should also provide health practitioners with a checklist for training staff under their supervision. The training provided by suppliers may need to be supplemented by additional training by those responsible for overseeing the testing with information specific to the business's requirements and circumstances (e.g. information provided in specific languages or use of pictures).

Why is training required?

Training in adequate sample collection and correct performance of the test is essential to minimise user errors which can impact test interpretation and accuracy.

All health practitioners or paramedics and persons operating under their supervision must be trained in the correct use of the device. Staff must also be trained in appropriate specimen collection and infection control procedures. Transmission-based precautions must also be used when collecting and handling potentially infectious specimens not just for SARS-CoV-2, but also for other infectious diseases.

Feedback from those already using these tests has confirmed the importance of ensuring adequate specimens are collected to avoid inaccuracies due to poor specimen collection, and the need for supervision of testing, particularly for the management of positive results. Both depend on appropriate training and supervision.

Can training be performed on-line?

Face-to-face training is preferable but interactive on-line training would be acceptable. All individuals undergoing training would still need to have access to samples of the test to practice with and be able to ask questions during the training session(s). Just providing a video for someone to watch would not be sufficient.

Why does the testing need to be supervised by a health practitioner?

Point of care testing by, or under the supervision of, a suitably qualified health practitioner, medical practitioner or paramedic allows for immediate clinical advice to be provided in relation to:

- the correct collection of the sample

- the correct interpretation of results
- appropriate patient management or treatment if required
- handling of positive results.

The practitioner is responsible for overseeing the way testing is conducted and encouraging individuals who test positive to check what they need to do next according to the directions of your local health authorities.

As different States and Territories may have different recommendations for rapid antigen testing and for reporting positive results, individuals should be referred to their website for any local requirements including:

- whether confirmatory PCR testing is required;
- any specific health advice including isolation requirements; and
- how and whether the result is required to be reported to your State or Territory health department.

Where it is not possible for a health practitioner to be physically present the supervision does not need to be direct. See question, *Does the Health Practitioner need to be on-site?*

What are the responsibilities of the health practitioner?

The health practitioner, medical practitioner or paramedic remains responsible for the conduct of testing. They must be available (either in person, or available on the phone or by videoconference) to provide assistance or advice, as required, to persons operating under their oversight in the correct use of the device and the interpretation of the test results.

The responsible practitioner must also ensure that anyone performing the test under their oversight is appropriately trained in:

- 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
- where relevant, protocols for recording results and any reporting requirements so they can advise individuals when they are required to report a positive test result to their state or territory health department
- 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.

Failure to appropriately oversee testing may amount to professional misconduct. The practitioner remains liable at all times for the conduct of the testing.

Is it okay for the sample for testing in a point-of-care test to be self-collected? Does self-collection of a specimen also need to be supervised?

Yes, samples may be self-collected, but for point-of-care tests this must be supervised by a person who has been trained in sample collection. This is an important step in the testing process.

Where a sample is self-collected by an individual, the collection must be supervised to verify patient identification and ensure an appropriate sample is collected. Poor sample collection is a common cause of error and can result in false negative results. Whoever is performing the actual rapid antigen test must also be able to verify which person the sample was collected from.

It is important to note if self-collection of a sample is necessary this must be conducted under the supervision of a person who has been trained in sample collection. The suppliers' instructions for use for rapid antigen tests are not intended for general consumer understanding. Therefore, the training is necessary to fully understand how to take samples correctly and where relevant, how to

correctly perform and interpret the test results.

For information on remote supervision see the question, *Can remote supervision of sample collection and testing be performed by video?*

What about testing performed remotely with a medical practitioner?

The conditions allow for rapid antigen tests to be supplied to medical practitioners who may arrange for the tests to be available at a clinic or other site that can facilitate supervision of the collection of the test via video. Trained staff would need to be available onsite to perform or supervise collection of the sample (if self-collected) and to perform the test during the consultation with the medical practitioner.

The test is only to be used to test staff of the organisation, business or institution, or a patient under the direct care of the medical practitioner.

The medical practitioner supervising testing via video must also be trained in the correct use of the device and the interpretation of the test results.

The use of a Medicare Benefits Schedule (MBS) item, telehealth or otherwise, is not appropriate for this form of testing service.

For information on remote supervision see the question, *Can remote supervision of sample collection and testing be performed by video?*

Can remote supervision of sample collection and testing be performed by video?

The conditions allow for point-of-care 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 employee being provided the test need to have access to a copy of the instructions for use that is in a language that is most easily understood by them.
- 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.

Employees who are themselves a relevant health practitioner for the purposes of the conditions on supply and use of rapid antigen tests (e.g. a registered nurses) are able to perform the test on themselves once they are trained in the correct use and interpretation of the test, including self-collection of a sample. Remote supervision is not required in this circumstance, but the business or organisation still needs protocols in place for recording such testing as mentioned in the criteria above.

Businesses or organisations wanting to implement rapid antigen testing of their staff should refer to the additional guidance on our 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 on-going competency. It is not sufficient to rely on the initial training provided by the supplier of the test.

Can Health Practitioners test themselves?

Employees who are themselves a relevant health practitioner for the purposes of the conditions on supply and use of rapid antigen tests (e.g. a registered nurses) are able to perform the test on themselves once they are trained in the correct use and interpretation of the test, including self-collection of a sample. The health practitioner and organisation still require protocols in place for recording such testing as mentioned in the question *Can remote supervision of sample testing be performed by video?*

Can Health Practitioners test their patients?

Yes, as a precautionary measure, health practitioners may choose to voluntarily screen patients under their care for COVID-19 but there is no requirement that they must do this. In some cases, this may be more convenient for patients than having to obtain test kits personally.

Any testing of patients would be through an arrangement between the particular healthcare professional and the patient. If healthcare practitioners wish to test patients using point of care tests, they are responsible for sourcing the test kits themselves. They can charge patients a reasonable amount as a privately billed service to recoup costs of testing, but the person being tested should first consent to any additional payments before being tested.

Individual patients who test positive will still be responsible for checking to see if they need to report their results to the relevant state of territory health authorities and to report positive results if required to do so.

Except for pharmacists, healthcare practitioners are not permitted to provide a general testing service for members of the public (i.e. for people who are not their patients who are preparing for or are in the course of a consultation).

Does the Health Practitioner need to be on-site?

So that rapid antigen tests are appropriately used, and the results interpreted correctly, use by relevant trained health practitioners and trained staff operating under their oversight ensures that appropriate advice can be provided in the correct use of the rapid test and the interpretation of the test results.

This is because it is critical that the nasopharyngeal swab samples are done correctly and that anyone who records a positive result from a rapid antigen test immediately isolates from others to avoid potential spread of COVID-19 infection. It is not acceptable practice to just repeat the rapid antigen test in the hope of the second test being negative.

The rapid antigen tests can still only be used and supplied as per the conditions of supply. See question *Where or who can the tests be supplied to?*

Can a business purchase tests for their workers?

Yes, a business can purchase point-of-care rapid antigen tests but only if it engages or employs a health practitioner or paramedic who will be responsible for performing the test or supervising the performance of the test by trained staff.

The health practitioner, and any staff under their supervision performing the test, must be trained in the correct use and interpretation of the test. The health practitioner also has other responsibilities related to supervision of testing. See additional responses to questions about training and supervision.

Businesses or organisations wanting to implement rapid antigen testing of their works should refer to the additional guidance on our 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 on-going competency. It is not sufficient to rely on the initial training provided by the supplier of the test.

Small businesses only need to have a health practitioner such as a nurse or pharmacist to be available on the phone or by videoconference to provide assistance or advice, as required, to persons under their supervision. For a small business, this may only need access to a couple of hours of a health practitioner's time (e.g. a pharmacist or nurse).

Can I advertise as COVID-19 rapid antigen test? What are the "advertising conditions" for rapid point of care tests?

Suppliers of COVID-19 rapid antigen tests and testing service providers need to make sure that any advertising of rapid antigen tests that is accessible to consumers (including advertising to businesses or organisations) is compliant with the *Therapeutic Goods Advertising Code*.

The Advertising Code specifies a number of requirements for these types of advertisements. For example, it requires advertisements to be balanced, accurate, substantiated and not misleading. Additionally, under the Advertising Code, advertisements:

- must be consistent with the directions/instructions for use of the advertised product
- must not exaggerate the efficacy or performance of the product or encourage inappropriate use
- must not be likely to lead people to delay necessary medical attention and
- must not be inconsistent with public health campaigns.

Importantly, it is a legal requirement to not state or imply that the advertised goods are approved or endorsed by the TGA or any other government authority.

Additionally, representations used in advertising that refer to COVID-19 require approval or authorisation by the TGA. The TGA has authorised legally-binding requirements for what advertisements for COVID-19 rapid antigen tests can and cannot say through a permission made under section 42DK of the *Therapeutic Goods Act 1989*, the Therapeutic Goods (Restricted Representations - COVID-19 Rapid Antigen Tests) Permission (No. 2) 2022.

Suppliers (Sponsors) of rapid antigen tests can advertise them to health professionals but steps must be taken to make sure any advertisements, if it is publicly viewable, are consistent with the s42DK advertising permission described above. Alternatively, advertising can be made only accessible by health professionals (e.g. through the use of firewalls, or a requirement to register to gain access to online advertising).

We have published guidance which explains how parties can lawfully advertise COVID-19 rapid antigen tests for supply to businesses and organisations, and meet the requirements set out in the advertising permission.

COVID-19 rapid antigen point of care tests cannot be advertised for home use or self-testing, and all advertisements for COVID-19 rapid antigen point of care tests that are in the public domain (such as on company websites) must prominently state that the tests cannot be supplied for self-testing.

More information on advertising requirements for rapid antigen self-tests can be found at Advertising COVID-19 rapid antigen point of care and self-tests (home use tests).

The TGA will take action in relation to any advertisements that do not meet the requirements.

Further information can be found at the Advertising Therapeutic Goods Hub.

Can the test be supplied via a distributor?

A sponsor can authorise a distributor to supply the rapid antigen tests on their behalf. This is usually via a contractual arrangement between the sponsor and distributor.

A distributor is acting on behalf of the sponsor and can only supply the device in accordance with the conditions including making sure all training and supervision requirements are met. A distributor must also maintain records relating to all supply of rapid antigen tests and be able to provide this information to the sponsor.

The sponsor remains responsible for supply of the device and all post-market monitoring and reporting responsibilities.

For more information contact us at IVDs@tga.gov.au or 1800 141 144.

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