Australian Government
Department of Health
Therapeutic Goods Administration

Q&As - Conditions of supply for rapid antigen tests

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

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

A list of all rapid antigen tests approved for supply in Australia is available on the TGA website (//www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia) and is regularly updated as new tests are approved or if tests are cancelled or withdrawn.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 a particular rapid antigen test.

Where do I purchase the tests from, how much do the tests cost and how often do I need to test?

A list of all rapid antigen tests approved for supply in Australia (//www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-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is available on the TGA website and is regularly updated as new tests are approved or if tests are cancelled or withdrawn.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. Please contact the relevant state or territory government or see their websites for how often mandatory tests are required.

Rapid antigen tests are not permitted to be sold to individuals for self-testing at home. See question on *Where or who can the tests be supplied to?* for further information.

Why aren't rapid tests that give results in 15 minutes used more widely rather than the PCR tests that take hours for results to come back?

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.

Some of these shortcomings can be partly, but not fully compensated by using rapid antigen tests more frequently (every few days) and ensuring that both those who test positive or people who have COVID-19 symptoms are urgently tested using a PCR test.

Rapid antigen tests may also be valuable alongside the confirmatory gold-standard PCR testing in an outbreak where there is high local disease prevalence (such as currently in Sydney). More rapid public health responses to testing can further reduce disease transmission.

Planning for the greater use of rapid antigen testing as part of Australia's COVID-19 testing strategy in the future is underway.

What is the accuracy of rapid antigen tests?

Rapid antigen tests can detect the virus in the acute phase of infection - especially in the week before symptoms are apparent, and the first week of symptoms being apparent.

In the wider Australian community settings where there are low rates of COVID-19, the tests are less accurate as there is a higher risk of both false positive and false negative results.

For this reason, whilst a goal of no or very low community transmission is being pursued, performing confirmatory testing by PCR is very important if someone gets a positive test from a rapid antigen test.

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

The TGA has approved a significant number of 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 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 healthcare professional involvement and the prohibition on self-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.

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 has been trained in the correct use and interpretation of the tests.

Use of the 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 for use by specified health practitioners at the point of care to the following:

a. Registered medical practitioners or paramedics, or an organisation, business or institution that employs or engages a registered medical practitioner or paramedic to perform or oversee performance of the test. The tests can only to be used to test employees or contractors of the organisation, business or institution, or a patient under the direct care of the medical practitioner or the paramedic.

b. 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.

c. Organisations, businesses, or institutions that employ or engage health practitioners or paramedics to conduct or oversee performance of the tests. For example, rapid antigen tests are being used in the mining sector consistent with these conditions. The tests can only be used to test staff or students of the organisation, business or institution, or a person who is a patient of a registered dental practitioner who requires an emergency dental procedure.

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 the tests be supplied to pharmacies or dental practices? Can a pharmacist or dentist carry out the test in a pharmacy or dental practice? They are already administering vaccines.

At present rapid antigen tests can only be supplied to pharmacies and dental practices for the purpose of testing staff of the organisation, business or institution. A dentist can also test a patient who requires an emergency dental procedure. The tests cannot be supplied to pharmacies for retail sale to consumers or to provide a general testing service.

The current priority is to drive greater testing in the workplace, aged and residential disability care and in other institutional settings. The Department of Health (including the TGA) will work with stakeholders over the coming months on regulatory and public health issues in anticipation of wider provision of tests, potentially to enable pharmacy based testing in the coming months and, at a later stage, possibly home or self-testing.

At present, permitting wider provision of tests would be critically dependent on achieving the vaccination rates as outlined in the National Plan to Australia's COVID-19 response (https://pmc.gov.au/national-plan-transition-australias-national-covid-response), and the establishment of systems that enable the electronic reporting and recording of rapid antigen test results.

At this stage of the pandemic, it is important to encourage people with possible COVID-19 symptoms to have a PCR test. The structures are in place for all PCR test results from existing testing facilities to be recorded and results reported back to those tested, and for isolation and contract tracing steps on positive individuals to commence without delay.

In the current Australian situation, it may be unwise to specifically encourage symptomatic or potentially infected individuals to 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.

Both issues will be continually monitored. Once vaccination coverage in Australia reaches higher levels, and there is confidence that disease prevalence is relatively stable in line with the National Plan to transition Australia’s COVID-19 response, these prohibitions may be reconsidered.

It is important that any community pharmacy considering a future rapid antigen testing approach takes into consideration the implications of testing in these environments, including:

- a procedure for notification of positive results to the relevant state or territory health authority so a follow up PCR test can be performed, and contact tracing initiated
- processes to maintain confidentiality of patient information

- a procedure for possible closure of the practice and isolation of staff if a positive result is received from a rapid antigen test, and
- any state and territory directions around rapid antigen testing.

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* (https://www.legislation.gov.au/Series/C2004A03952) (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:
>
> 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

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) (https://www.ahpra.gov.au/About-AHPRA.aspx#:~:text=The%20Australian%20Health%20Practitioner%20Regulation%20Agency%20%28
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 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. 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 businesses 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 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 false 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?

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
- arrangements for confirmatory testing and notifications to health authorities for the purpose of surveillance and contact tracing.

The practitioner is also responsible for the supervision of the way testing is conducted and making sure records are maintained for the individual being tested. Currently, with rapid antigen tests, there is no automated process for recording and including the results in an individual's patient record or for automatically notifying state and territory health authorities of a positive test.

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 under their supervision 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 supervision 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
- protocols for recording results and requirements for notification of positive results
- protocols and referral processes for recollection and confirmatory testing
- 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 supervise testing may amount to professional misconduct. The practitioner remains liable at all times for the conduct of the testing.

What requirements are there for reporting the results of testing for monitoring and contract tracing?

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) (https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-novel-coronavirus.htm).

These guidelines outline Australia's national minimum standard for surveillance, laboratory testing and contact management for COVID-19. There may be additional state and territory requirements that need to be complied with.

Failure to manage positive results (including confirmatory testing) can have significant public health consequences.

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

Yes, samples may be self-collected but 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 direct 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.

Further information on self-collection of specimens can be found in advice from members of the Public Health Laboratory Network (https://www.health.gov.au/resources/publications/phln-guidance-on-laboratory-testing-for-sars-cov-2-the-virus-that-causes-covid-19).

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 rapid antigen tests to be supplied to business or organisations that employ/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 under their supervision. 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 attend on-site training by a health practitioner 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.

Please note, 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 (//www.tga.gov.au/resource/covid-19-rapid-antigen-tests-guidance-and-checklist-businesses) 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.

Why is home testing not allowed?

The supply of home tests for COVID-19 is currently illegal as COVID-19 is a serious disease and testing should be performed by a suitably qualified health practitioner who is able to provide immediate clinical advice and treatment if required.

There is also a potential risk that some individuals could be motivated to conceal or not report a positive test, especially if they felt that their symptoms were mild and, for example they might lose employment income, be unable to go on holiday, or miss an important family event.

Although these tests can detect the virus in the acute phase of infection from symptomatic patients, in community settings where there are low rates of COVID-19 there is a high risk of false positive and false negative results and therefore the results can be susceptible to misinterpretation. This risk increases with inadequate sample collection.

Can a freight company or other business purchase tests for their workers?

Yes, a freight company or other business can purchase 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 practitioner and any staff under their supervision performing the test must be trained in the correct use and interpretation of the test. The practitioner also has other responsibilities related to supervision of testing. Please 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 (//www.tga.gov.au/resource/covid-19-rapid-antigen-tests-guidance-and-checklist-businesses) 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.

I am an interstate freight business will the State/Territory government accept rapid antigen testing for drivers?

Each State and Territory have their own conditions around what is required and accepted for testing including what is acceptable for the three-day testing in NSW.

It should also be noted that drivers may self-collect a sample under supervision but the test itself must be performed or supervised by a fully trained health practitioner, medical practitioner or paramedic unless the criteria for remote supervision is met, see question on remote supervision. For further information see questions on training and supervision.

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* (https://www.legislation.gov.au/Series/F2018L01524).

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 2021 (//www.tga.gov.au/advert-exempt/therapeutic-goods-restricted-representations-covid-19-rapid-antigen-tests-permission-2021) .

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 (//www.tga.gov.au/resource/covid-19-rapid-antigen-tests-guidance-and-checklist-businesses) 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 tests cannot be advertised for home use or self-testing, and all advertisements for COVID-19 rapid antigen tests that are in the public domain (such as on company websites) must prominently state that the tests cannot be supplied for self-testing.

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 (//www.tga.gov.au/hubs/advertising-therapeutic-goods).

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 please contact us at COVIDtests@tga.gov.au (mailto:COVIDtests@tga.gov.au) **or 1800 141 144.**

Category: Medical devices/IVDs

Tags: medical devices, COVID-19 tests, rapid antigen tests, businesses
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