Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 rapid antigen point-of-care and self-tests

28 September 2021

Timeframe for rapid antigen self-tests for COVID 19 for home use

To support the safe use of rapid antigen self-tests and following extensive consultation, the Therapeutic Goods Administration (TGA) will make a new regulation (Specification) by 1 October 2021 that will allow companies to formally apply for TGA regulatory approval after 1 October to legally supply their self-tests for use at home in Australia after 1 November 2021.

This is an important step in supporting the National Plan to transition Australia's National COVID-19 Response and aligns with the timeframe where it is expected that approximately 70 % of Australians will be double vaccinated.

Individual tests will require TGA approval and inclusion in the Australian Register of Therapeutic Goods (ARTG) as for all other testing kits. The TGA has already commenced the review of data and information for self-tests for those suppliers who have responded to the registration of interest process (//www.tga.gov.au/registration-interest).

Our priority continues to be working with suppliers and manufacturers of self-tests to ensure:

- instructions for use are written in a way that all consumers can understand
- suppliers having appropriate support available for example, via a You-tube video, 1800 call number, website fact sheets for consumers to seek help or ask questions
- usability testing has been successful with untrained, unsupervised users
- self-tests perform satisfactorily against variants such as Delta, noting that many tests in the international market were developed prior to the Delta variant becoming predominant

It is important that the appropriate systems are in place, including by State and Territories, to ensure the reliable use of these tests at home occurs at the earliest possible time, including enabling any consumer who has a positive rapid antigen test result is supported to immediately have a confirmatory PCR test at a COVID-19 testing centre.

The use of COVID-19 rapid antigen point-of-care tests is one part of Australia's strategy to combat COVID-19. The following information is provided so that rapid antigen tests are supplied for use by relevant health practitioners, and in appropriate circumstances. The Therapeutic Goods Administration (TGA) is progressing work that would allow the provision of self-tests (home-use tests) for COVID-19 in the future. Information and guidance are also provided below to allow sponsors to register their interest in supplying home-use tests.

How testing works for COVID-19

There are a number of ways for how we test for COVID-19 (//www.tga.gov.au/how-testing-works-covid-19) in Australia.

COVID-19 test kits included in the ARTG for legal supply in Australia

All COVID-19 test kits approved by the TGA for inclusion in the Australian Register of Therapeutic Goods (ARTG) are listed on the COVID-19 test kit (//www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia) page.

To find approved rapid antigen test kits, select 'Point-of-care test' under 'show only' and sort by 'Laboratory or Point of care test'.

All importers of COVID-19 test kits must apply for, and be granted, an import permit for all consignments of COVID-19 test kits that are imported into Australia, unless the importer can demonstrate that the goods are for personal use only or are entirely synthetic.

To apply for an import permit, please refer to BICON import permits (https://www.agriculture.gov.au/import/online-services/bicon/bicon-permit).

COVID-19 rapid antigen self-tests

Registration of interest for sponsors of home-use tests

The supply of home tests for COVID-19 is currently prohibited however, the TGA is progressing work that would allow the provision of these tests in the future. Whilst a framework to support self-testing is being developed, potential sponsors are invited to register an expression of interest in supplying COVID-19 rapid antigen self-tests (//www.tga.gov.au/registration-interest). Note: the TGA will not be accepting applications for inclusion at this stage.

Checklist for information that sponsors will be asked to provide in response to their registration of interest to supply a COVID-19 rapid antigen self-test.

- COVID-19 rapid antigen self-test - Supporting Data Checklist (//www.tga.gov.au/sites/default/files/registration-of-interest-rats.docx)

Guidance about COVID-19 self-tests for industry

We have published the following guidance to assist sponsors and manufacturers to prepare their documentation for when applications are allowed to be submitted for COVID-19 rapid antigen self-tests.

COVID-19 rapid antigen self-tests - Guidelines on performance requirements and risk mitigation strategies

Information about the Therapeutic Goods Administration's (TGA) requirements concerning performance requirements (e.g. analytical and clinical sensitivity and specificity) risk mitigation, usability studies and labelling requirements for COVID-19 rapid antigen self-tests.

- COVID-19 rapid antigen self-tests - Performance requirements and risk mitigation strategies (//www.tga.gov.au/resource/covid-19-rapid-antigen-self-tests)

Software for use with COVID-19 rapid antigen self-tests – Guidelines on regulatory requirements

Information about the Therapeutic Goods Administration's (TGA) requirements for software and apps designed for use with COVID-19 rapid antigen self-tests.

- Software for use with COVID-19 rapid antigen self-tests - Regulatory requirements (//www.tga.gov.au/resource/software-use-covid-19-rapid-antigen-self-tests)

Conditions specific to COVID-19 rapid antigen point-of-care tests

The following four conditions are imposed on the supply of COVID-19 rapid antigen tests included in the Register:

1. The person in whose name the device is included in the Register (the ***sponsor***) may only supply the device to one or more of the following:
    a. a laboratory that is an accredited pathology laboratory within the meaning of the *Health Insurance Act 1973*;
    b. a medical practitioner who is registered under a law of a state or territory to practice medicine, a person registered under a law of a state or territory to practice paramedicine (a ***paramedic***), or an organisation, business or institution that employs or engages a medical practitioner or a paramedic, where:
        i. the medical practitioner or the paramedic is responsible for performing or supervising the performance of the test; and
        ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result; and
        iii. the device is only 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;
    c. a residential care or aged care facility, or a home care service provider, that employs or engages a health practitioner within the meaning of the *Therapeutic Goods Act 1989* or a paramedic (as defined in paragraph (b)), where:

i. the health practitioner or the paramedic is responsible for performing or supervising the performance of the test; and

ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result; and

iii. the device is only used to test residents, employees or contractors of, or visitors to, the residential care or aged care facility, or clients, employees, or contractors of the home care service provider;

d. an organisation, business or institution that employs or engages a health practitioner within the meaning of the *Therapeutic Goods Act 1989* or a paramedic (as defined paragraph (b)) where:

i. the health practitioner or the paramedic is responsible for performing or supervising the performance of the test; and

ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result; and

iii. the device is only used to test employees, contractors or students of the organisation, business or institution, or a person who is a patient of a practitioner registered under a law of the state or territory to practice dentistry and who requires an emergency dental procedure;

e. a department of the Commonwealth, state or territory, with responsibility for health, or a department or other agency of the Commonwealth, state or territory acting on its behalf.

2. The device must not be supplied for the purpose of self-testing.

3. The sponsor of the device must provide training to a person mentioned in subparagraphs (1)(b)(ii), (1)(c)(ii) or (1)(d)(ii) in the correct use of the device and the interpretation of the test result, prior to that person performing or supervising the performance of the test.

4. The sponsor must maintain records that demonstrate the device has been supplied in compliance with these conditions.

Condition 1(a)

Accredited pathology laboratories (https://www.nata.com.au/accredited-facility) in this context are pathology laboratories accredited by the National Association of Testing Authorities (NATA) and/or Royal College of Pathologists of Australasia (RCPA) for Human Pathology Testing (under the *Health Insurance Act 1973*) and are eligible for claiming to Medicare for approved pathology services.

Condition 1(b)

Condition (1)(b) includes supply to medical practitioners, paramedics or organisations, businesses or institutions that employ or engage a medical practitioner or paramedic registered with the Australian Health Practitioner Regulatory Agency (AHPRA) (https://www.ahpra.gov.au/) under the Health Practitioner National Law (https://www.ahpra.gov.au/About-AHPRA/What-We-Do/Legislation.aspx) as is in force in each state and territory. A medical practitioner or paramedic may perform or oversee the performance of the test by a person under their supervision, for example a registered or enrolled nurse. The medical practitioner or paramedic remains responsible for the conduct of the testing and must be available to provide assistance or advice as required to persons under their supervision in the use of the device and the interpretation of the test results. All staff need to be trained in the correct use of the test.

Condition 1(c)

Condition (1)(c) includes supply to residential care (i.e. disability and rehabilitation facilities),aged care facilities and home care providers that employ or engage paramedics or health practitioners (including but not limited to medical practitioners or registered (Division 1) or enrolled (Division 2) nurses) who are responsible for conducting or overseeing the performance of the test. The reference to health practitioner in this condition is a reference to a person within the meaning of that term in section 3 of the *Therapeutic Goods Act 1989*. A paramedic is a person registered under a law of a state or territory to practice paramedicine. Personal care and disability support workers are not health practitioners for the purposes of this condition.

Condition 1(d)

Condition (1)(d) allows supply organisations, businesses or institutions that employ or engage paramedics or health practitioners who are responsible for performing or supervising the performance of a test on their staff. The reference to health practitioner in this condition is a reference to a person within the meaning of that term in section 3 of the *Therapeutic Goods Act 1989*. A paramedic is a person registered under a law of a state or territory to practice paramedicine.

All health practitioners including paramedics, and persons under their supervision must be trained in the correct use of the device and the interpretation of the test results. The health practitioner or paramedic remains responsible for the conduct of testing and must be available 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.

Condition 1(e)

Condition (1)(e) allows for supply of the device to a department or other agency of the Commonwealth, a state or territory, that has arrangements in place to procure COVID-19 test kits on behalf on the Commonwealth, state or territory departments with responsibility for health. For reference, a general list of government departments and agencies may be accessed at Australian government departments and agencies (https://www.australia.gov.au/about-government/departments-and-agencies/list-of-departments-and-agencies).

Conditions (3) and (4)

Conditions (3) and (4) require the sponsor to provide health practitioners training in the correct use of the device and interpretation of results and keep records of such training.

Once trained, a health practitioner can train persons under their supervision to conduct the test. The health practitioner would be responsible for maintaining records of this training.

What is meant by supervision of testing?
Supervision is a key responsibility for controlling the risks to patient safety and welfare that may arise while providing a testing service. Supervision of testing goes to the professional conduct of a practitioner. Failure to appropriately supervise testing may amount to professional misconduct. The practitioner remains liable at all times for the conduct of the testing.

Once appropriately trained in the correct use of the device, persons under the supervision of a health practitioner (as specified in Conditions (1)(b) to (1)(d)) may perform the test. The relevant health practitioner responsible for supervision of testing is required to ensure all persons performing the test (including sample collection, performing tests and interpreting test results) under their supervision are appropriately trained in all matters related to good testing practice, including:

- 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; and
- protocols for reporting any problems or adverse events associated with performance of the test to the Therapeutic Goods Administration.

Q&A - Conditions of supply for rapid antigen tests

We have developed a number of questions and answers to provide information about what tests are approved, and the supply and use of these tests.

- Conditions of supply for rapid antigen tests - questions and answers (//www.tga.gov.au/qas-conditions-supply-rapid-antigen-tests)

Guidance for businesses wanting to implement testing in the workplace

We have published guidance on understanding the key considerations for establishing COVID-19 rapid antigen point-of-care testing in your workplace.

- COVID-19 Rapid Antigen Point-of-Care Tests - Guidance for implementation and checklist for businesses (//www.tga.gov.au/resource/covid-19-rapid-antigen-tests-

guidance-and-checklist-businesses)

Guidance for advertising COVID-19 rapid antigen tests

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.

- Advertising COVID-19 Rapid Antigen Tests (//www.tga.gov.au/advertising-covid-19-rapid-antigen-tests)
- Advertising Permission - Restricted Representations - COVID-19 Rapid Antigen Tests (//www.tga.gov.au/advert-exempt/therapeutic-goods-restricted-representations-covid-19-rapid-antigen-tests-permission-no-2-2021)

Prohibitions and restrictions by State and Territory governments

Some states have prohibited or restricted use of SARS-CoV-2 Rapid Antigen Tests as an acute illness diagnostic tool for COVID-19. Please visit the Further information can be found on the Western Australian (https://www.wa.gov.au/government/publications/prohibition-the-use-of-rapid-antigen-testing) and South Australian (https://www.covid-19.sa.gov.au/emergency-declarations/prohibition-of-point-of-care-serology-tests)* government websites for further information.

***Note** that this does not apply to employees of SA Pathology or the SA Department of Health.

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

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