



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## **Applying for TGA assessment of a COVID-19 test for inclusion in the ARTG**

10 August 2021

COVID-19 infections are diagnosed using tests called in vitro diagnostic medical devices (IVDs). The Therapeutic Goods Administration (TGA) is working with IVD suppliers to ensure that there are tests available to support efforts in managing the COVID-19 emergency.

This page provides information for sponsors (i.e. suppliers/importers) that wish to submit an application for expedited TGA assessment for inclusion of a COVID-19 test in the Australian Register of Therapeutic Goods (ARTG). Sponsors are encouraged to review the information on this page in conjunction with the [Legal Supply of COVID-19 test kits \(//www.tga.gov.au/legal-supply-covid-19-test-kits\)](http://www.tga.gov.au/legal-supply-covid-19-test-kits) page.

**Note:** This is current advice relating to the inclusion of COVID-19 tests in the ARTG. As the COVID-19 situation changes, this advice may be amended. Please contact us at [devices@tga.gov.au](mailto:devices@tga.gov.au) (<mailto:devices@tga.gov.au>) or 1800 141 144 if you need further information.

**On this page:** [Applications to supply COVID-19 tests will be prioritised](#) | [Process for applying for inclusion of a COVID-19 test in the ARTG](#) | [Conditions on all COVID-19 tests approved for ARTG inclusion](#) | [Post-market review of serology COVID-19 point-of-care tests](#) | [More information](#)

### **Applications to supply COVID-19 tests will be prioritised**

We encourage sponsors to submit an application for inclusion of their COVID-19 tests in the ARTG.

Please note that sponsors are not required to request or submit a priority review as all applications in relation to COVID-19 tests are already being expedited as a matter of priority in assessment queues. Further prioritisation of particular COVID-19 tests will be guided by advice from the Chief Medical Officer, the Office of Health Protection and the Public Health Laboratory Network.

### **Process for applying for inclusion of a COVID-19 test in the ARTG**

The TGA will provide sponsors who are new to the Australian market with information on the regulatory requirements for the inclusion of COVID-19 tests in the ARTG.

As a potential sponsor of a COVID-19 test kit, you will need to submit and have your [manufacturer's evidence \(//www.tga.gov.au/manufacture-evidence-medical-devices-and-ivd-medical-devices\)](https://www.tga.gov.au/manufacture-evidence-medical-devices-and-ivd-medical-devices) (conformity assessment certification) accepted by the TGA prior to being able to submit your IVD application. Once an IVD application is submitted and the application fee paid, the TGA will contact you and advise what information you will be required to supply.

In the first instance, the TGA website provides guidance on the information that should be included in the technical files of an application and a step-by-step guide to the ARTG inclusion process:

- [Medical device inclusion process \(//www.tga.gov.au/publication/medical-device-inclusion-process\)](https://www.tga.gov.au/publication/medical-device-inclusion-process) - step-by-step guide
- [Overview of medical devices and IVD regulation \(//www.tga.gov.au/sme-assist/medical-devices-regulation-introduction\)](https://www.tga.gov.au/sme-assist/medical-devices-regulation-introduction).

Please note, based on experience gained from the [post market review of serology-based COVID 19 point-of-care devices \(//www.tga.gov.au/post-market-evaluation-serology-based-point-care-tests\)](https://www.tga.gov.au/post-market-evaluation-serology-based-point-care-tests), the TGA expects clinical performance studies to be provided that clearly demonstrate the sensitivity of the device according to:

- the immunoglobulin type (e.g., IgG, IgM and combined IgM, IgG); and
- the days post onset of symptoms.

This information also needs to be included in the instructions for use (IFU) provided with the device so that the user can make an informed decision about how to interpret the results taking into consideration the clinical presentation of the patient and the time since the onset of symptoms. Clear warnings need to be provided in the IFU about the potential for negative results if testing is performed in the acute phase of infection and the need for further laboratory testing.

The TGA may request further information throughout the assessment process. We understand that many of these tests are being developed very quickly and that some supporting information, such as real-time stability studies, may not yet be available.

**Note:** Please note an application will not be progressed nor a decision made until the associated application and audit fees have been paid.

**Note:** A COVID-19 test can only be supplied once a sponsor receives a notice of the ARTG inclusion entry number.

The ongoing responsibilities of sponsors are described further in the [Australian Regulatory Guidelines for Medical Devices \(ARGMD\) \(//www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd\)](https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd). We encourage all sponsors of COVID-19 tests to review this information.

**Note:** We are committed to supporting sponsors in their understanding of their regulatory requirements for the supply of COVID-19 tests. Please contact us at [devices@tga.gov.au](mailto:devices@tga.gov.au) (<mailto:devices@tga.gov.au>) or 1800 141 144 if you have any questions regarding this process.

## **Conditions on all COVID-19 tests approved for ARTG inclusion**

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All COVID-19 tests that are included in the ARTG based on an expedited assessment process are subject to additional non-standard conditions, that inform post-market validations as experience and knowledge around COVID-19 diagnostic testing grows.

The conditions require that additional evidence to support the ongoing safety and performance of the device be provided to the TGA within 12 months of approval. The TGA will advise sponsors when additional evidence is required to be provided.

### **Additional conditions specific to COVID-19 serology and rapid antigen point-of-care tests**

Additional conditions are imposed on the supply of COVID-19 serology-based tests and rapid antigen (viral protein) tests for use at the point-of-care as it is considered that the correct interpretation of results obtained from these tests requires the involvement of a suitably qualified healthcare professional.

The correct interpretation of test results in conjunction with the clinical presentation of a patient is critical to informing patient management and minimisation of further transmission of the virus. Accurate identification of a COVID-19 infection based on results obtained from serology-based and rapid antigen point-of-care tests requires testing by suitably qualified persons with an understanding of how the viral infection develops, the different stages of infection and subsequent antibody response profile.

The misinterpretation of serology-based and rapid antigen point-of-care test results presents a grave risk to public health, which could result in serious illness and death of the patient and other persons that the patient comes into contact with. Testing for COVID-19 should be conducted in conjunction with an appropriate healthcare professional who can provide an individual with appropriate advice and treatment.

Transmission-based precautions must also be used when collecting specimens from patients with a communicable disease, which should be regarded as potentially infectious not just for SARS-CoV-2 (the virus that causes the disease called COVID-19), but also for other infectious diseases. Staff must be trained in appropriate specimen collection and infection control procedures.

For these reasons, the additional non-standard conditions of inclusion in the ARTG apply to serology-based and rapid antigen point-of-care tests for COVID-19:

### **Conditions specific to COVID-19 serology point-of-care tests**

The following non-standard conditions of inclusion in the ARTG apply to serology-based point-of-care tests for COVID-19.

1. The person (the sponsor) in relation to whom the Device is included in the ARTG may only supply the Device to:
  - a. laboratories that are accredited pathology laboratories; and/or
  - b. medical practitioners who are registered under a law of a State or Territory; and/or
  - c. health care professionals in residential and aged care facilities; and/or
  - d. the Commonwealth, State or Territory department of health; and/or
  - e. an agency of the Commonwealth, State or Territory acting on behalf of the Commonwealth, State or Territory department of health.

Further clarification relating to the specific conditions of supply is provided below.

**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 organisations that employ a medical practitioner 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 may then conduct/oversee/guide the performance of testing by a registered/enrolled nurse.

**Condition 1(c)**

Condition 1(c) includes supply to residential (i.e. disability and rehabilitation facilities) and aged care facilities that employ health care professionals (this includes either a medical practitioner as specified in 1(b) or a registered/enrolled nurse) who will conduct the test. This condition would not allow for testing in a home care setting.

**Condition 1(d) and (e)**

1(d) and (e) of the conditions allow for supply of a device to the Government or an acceptable agency included in the list of Australian government departments and agencies (<https://www.australia.gov.au/about-government/departments-and-agencies/list-of-departments-and-agencies>) and has been appointed/contracted to acquire COVID-19 test kits on behalf on the Commonwealth, State or Territory department of health.

**Note:** The above conditions **do not** currently allow the supply of COVID-19 serology-based tests for use at the point-of-care to other healthcare professionals (i.e. pharmacists).

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

The following non-standard conditions of inclusion in the ARTG apply to rapid antigen point-of-care tests for COVID-19.

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, or an organisation, business or institution that employs or engages a medical practitioner, registered to practice under a law of a state or territory, where the practitioner is responsible for performing or supervising the performance of the test, and both the practitioner and a person acting under the practitioner's supervision to perform the test have received training in the correct use of the device and interpretation of the test result;
  - c. a residential care or aged care facility that employs or engages a health practitioner, within the meaning of the *Therapeutic Goods Act 1989*, where the practitioner is responsible for performing or supervising the performance of the test, and both the practitioner and a person acting under the practitioner's supervision to perform the test have received training in the correct use of the device and interpretation of the test result;
  - d. (d) an organisation, business or institution that does not have the primary function of providing healthcare services but employs or engages a health practitioner within the meaning of the *Therapeutic Goods Act 1989*, where the practitioner is responsible for performing or supervising the performance of the test, where both the practitioner and a person acting under the practitioner's supervision to perform the test have received training in the correct use of the device and interpretation of the test result;
  - 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 practitioner mentioned in paragraphs (1)(b) to (d) in the correct use of the device and the interpretation of the test result, prior to that practitioner 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 the Royal College of Pathologists of Australasia (RCPA) for Human Pathology

Testing (under the *Health Insurance Act 1973*) and are eligible for claiming medicare benefits for approved pathology services.

### **Condition (1)(b)**

Condition (1)(b) includes supply to medical practitioners or organisations, businesses or institutions that employ or engage a medical practitioner registered with the [Australian Health Practitioner Regulatory Agency \(AHPRA\)](https://www.ahpra.gov.au/) (<https://www.ahpra.gov.au/>) under the [Health Practitioner National Law](https://www.ahpra.gov.au/About-AHPRA/What-We-Do/Legislation.aspx) (<https://www.ahpra.gov.au/About-AHPRA/What-We-Do/Legislation.aspx>) as is in force in each state and territory. A medical practitioner 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 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.

In a remote situation, this condition could also extend to enabling a medical practitioner to supervise the self-collection, performance and interpretation of the test by a person under their care. However, such supervision must be undertaken personally by the practitioner within the course of the consultation. Trained staff would also 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.

### **Condition (1)(c)**

Condition (1)(c) includes supply to residential care (i.e. disability and rehabilitation facilities) and aged care facilities that employ or engage 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. Personal care and disability support workers are not considered health practitioners for the purposes of this condition.

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.

### **Condition (1)(d)**

Condition (1)(d) allows supply organisations, businesses or institutions (that do not have the primary the function of providing healthcare services) that employ or engage health practitioners who are responsible for performing or supervising the performance of a test. Where samples are self-collected by individuals, the collection must be supervised to verify patient identification, sample collection, test performance and the interpretation of test results. An individual who is not a health practitioner cannot perform the test on their own samples.

All health practitioners and persons under their supervision must be trained in the correct use of the device and the interpretation of the test results. A health practitioner 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 arrangement 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 \(https://www.australia.gov.au/about-government/departments-and-agencies/list-of-departments-and-agencies\)](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 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 \(//www.tga.gov.au/qas-conditions-supply-rapid-antigen-tests\)](https://www.tga.gov.au/qas-conditions-supply-rapid-antigen-tests)

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## **Post-market review of serology COVID-19 point-of-care tests**

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A post-market validation is being performed on all TGA approved serology COVID-19 point-of-care tests. Upon approval, sponsors will be required to provide samples to the TGA for validation.

The TGA will advise sponsors when samples are to be sent for validation. For further information, see [Post-market review of COVID-19 point-of-care tests \(//www.tga.gov.au/post-market-review-covid-19-point-care-tests\)](http://www.tga.gov.au/post-market-review-covid-19-point-care-tests).

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## **More information**

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### **COVID-19 IVD classification and GMDN collective term**

The classification rules for IVDs are provided in Schedule 2A of the [\*Therapeutic Goods \(Medical Devices\) Regulations 2002\*](https://www.legislation.gov.au/Details/F2020C00112) (<https://www.legislation.gov.au/Details/F2020C00112>). Currently the TGA is processing COVID-19/SARS-CoV-2 assays as Class 3 IVDs.

If you intend to submit an application for inclusion in the ARTG for a COVID-19 IVD, an appropriate level 3 Global Medical Device Nomenclature (GMDN) collective term in the TGA database is "Severe acute respiratory syndrome-associated coronavirus IVDs" CT772. If your device is for multiple pathogens your application may require a different GMDN term. Please contact us at [devices@tga.gov.au](mailto:devices@tga.gov.au) (<mailto:devices@tga.gov.au>) or 1800 141 144 for further information.

### **Conformity Assessment (Manufacturer's evidence)**

For Class 3 IVDs, manufacturers are required to implement a full quality management system (QMS) that includes design and development (i.e. not just manufacture or production) - refer to schedule 3, part 1, clause 1.1 of the [\*Therapeutic Goods \(Medical Devices\) Regulations 2002\*](https://www.legislation.gov.au/Details/F2020C00112) (<https://www.legislation.gov.au/Details/F2020C00112>). Full quality management system assessment to the requirements of ISO 13485:2016 would include assessment to Clause 7.3 for Design and Development.

The QMS certificate needs to be issued by an acceptable certification body. The manufacturer's scope of QMS certification also needs to cover manufacture of the kind of device being applied for. If the scope is not clear, the TGA may request a copy of the QMS audit report to confirm whether a manufacturer's certification covers the manufacture of a particular type of COVID-19 test.

Further [guidance on acceptable evidence \(//www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds\)](http://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds) can be found on the TGA website.

### **Associated fees for a Class 3 IVD**

The TGA publishes information on the current [fees and charges for therapeutic goods](http://www.tga.gov.au/schedule-fees-and-charges) ([//www.tga.gov.au/schedule-fees-and-charges](http://www.tga.gov.au/schedule-fees-and-charges)). The fees to include a Class 3 IVD medical device in the ARTG for the 2019/20 financial year are as follows:

- Application fee - \$1,070
- Audit assessment fee (if the TGA requires the IVD to be selected for mandatory audit) - \$7,200
- Annual charge - \$700.

Regulation 5.3(1)(j) of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](https://www.legislation.gov.au/Details/F2020C00112) (<https://www.legislation.gov.au/Details/F2020C00112>) prescribes the kind of IVD medical device that is required to be selected for audit.

### COVID-19 updates

The TGA has a [Coronavirus \(COVID-19\) information page](http://www.tga.gov.au/collection/covid-19) ([//www.tga.gov.au/collection/covid-19](http://www.tga.gov.au/collection/covid-19)) which is updated as new information becomes available.

To keep up to date with the latest developments in relation to COVID-19, visit the [coronavirus \(COVID-19\) health alert page](https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert) (<https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert>) on the Department of Health website.

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**Category:** Medical devices/IVDs

**Tags:** medical devices, COVID-19 tests, rapid antigen tests, employers

**URL:** <https://www.tga.gov.au/node/904114> (<https://www.tga.gov.au/node/904114>)



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