We've released a trial (beta) version of a new ARTG search tool Please try it and provide feedback. (https://compliance.health.gov.au/artg/)

Australian Government
Department of Health
Therapeutic Goods Administration

Instructions for sponsors who have interest in supplying a COVID-19 self-test

27 January 2022

The process for submitting an application for a COVID-19 self-test will depend on whether you:

- are a new sponsor to the TGA
- have an existing ARTG entry for a COVID-19 test
- have an existing application.

> Prior to submitting your application, please ensure you have reviewed the following documents:
>
> 1. COVID-19 Rapid antigen self-tests - Performance requirements and risk mitigation strategies (//www.tga.gov.au/resource/covid-19-rapid-antigen-self-tests)
> 2. Software for use with COVID-19 rapid antigen self-test - Regulatory requirements (//www.tga.gov.au/resource/software-use-covid-19-rapid-antigen-self-tests)
> 3. COVID-19 rapid antigen self-test - Supporting Data Checklist (//www.tga.gov.au/covid-19-rapid-antigen-self-tests-home-use)
> 4. Advertising COVID-19 rapid antigen point-of-care tests and self-tests (home use tests) (//www.tga.gov.au/advertising-covid-19-rapid-antigen-point-care-tests-and-self-tests-home-use-tests)
>
> If you have previously accessed the supporting data checklist please check for an updated version.

General instructions

Importing COVID-19 test kits

In addition to formally submitting your IVD application to the TGA you will need to consider if you need to apply for a Biosecurity Import Permit (https://www.agriculture.gov.au/import/online-services/bicon).

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, for lateral flow test kits, meet the import conditions published on the Australian Biosecurity Import Conditions (https://bicon.agriculture.gov.au/BiconWeb4.0/ImportConditions/Conditions?EvaluatableElementId=613730&Path=UNDEFINED&UserContext=External&EvaluationStateId=576353fe-b347-4f93-b070-4932aa7b062d&CaseElementPk=1660899&EvaluationPhase=ImportDefinition&HasAlerts=True&HasChar (BICON).

The Department of Agriculture, Water and the Environment has published a new webpage providing information about the import of COVID-19 Rapid Antigen Test Kits (https://www.awe.gov.au/biosecurity-trade/import/online-services/bicon/bicon-permit/rapid-antigen-test-kits) for both commercial and personal use.

To minimise price gouging and limit exportation of COVID-19 rapid antigen tests, an emergency determination (https://www.legislation.gov.au/Details/F2022L00019) under section 477 of the *Biosecurity Act 2015* was made. The determination also outlines the enforcement of price gouging and exceptions for exporting COVID-19 rapid antigen tests. Further information is available on the Australian Border Force (https://www.abf.gov.au/importing-exporting-and-manufacturing/prohibited-goods/categories/covid-exports) website.

Post-market assessment

Post-market assessment of rapid antigen tests (//www.tga.gov.au/post-market-review-antigen-and-rapid-antigen-tests), including self-tests, may be requested. The TGA will advise the quantity and when samples are required to be provided for any post-market evaluations (the TGA can request these samples under section 41FN(2) of the Act).

Regulatory Affairs Consultants

You may wish to engage with a regulatory affairs consultant, who can offer services, including advice and assistance, in relation to regulatory requirements. Information about regulatory consultants (//www.tga.gov.au/regulatory-affairs-consultants) is available on the TGA website.

Sponsors without existing ARTG entry for a COVID-19 test

This section is for:

- new sponsors to the TGA
- sponsors without an existing ARTG entry for a COVID-19 test with an assigned ARTG number

- sponsors with an application for a COVID-19 test under review

Sponsors new to the market

The TGA can provide suppliers who are new to the Australian market with information on the Australian requirements for the supply of safe and accurate COVID-19 tests.

In the first instance, the TGA website has guidance for those new to Australian medical device and IVD regulation (//www.tga.gov.au/sme-assist/medical-devices-regulation-introduction). The TGA website also provides advice on the information that should be included in the technical files (//www.tga.gov.au/publication/application-audit-technical-file-review-ivd-medical-device-applications) of an application for an IVD medical device.

Initial ARTG inclusion application

The TGA provides sponsors with guidance on how to include an IVD medical device on the ARTG (//www.tga.gov.au/publication/medical-device-inclusion-process).

A breakdown of the steps for including a COVID-19 test kit in the ARTG follows:

Step 1.

You will be required to apply for a client ID to have access to the TGA business services portal. Information on how to apply for a client ID can be found on the TGA website (//www.tga.gov.au/book-page/step-3-accessing-tga-business-services). You can submit the for either by clicking "submit" in the form or by sending it directly to eBS@health.gov.au (mailto:eBS@health.gov.au)

Step 2.

You will be required to submit manufacturer evidence of conformity assessment to support your application for inclusion. Information on how to submit manufacturer evidence can be found on the TGA website at Manufacturer evidence for medical devices and IVD medical devices (//www.tga.gov.au/manufacturer-evidence-medical-devices-and-ivd-medical-devices).

Refer to the guidance (//www.tga.gov.au/comparable-overseas-regulators-medical-device-applications) and below table related to acceptable kinds of Manufacturer Evidence that you can use as evidence of conformity assessment for a Class 3 IVD.

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/Series/F2002B00237). Full quality management system assessment to the requirements of ISO 13485:2016 would include assessment to Clause 7.3 for Design and Development.

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

Types of Quality Management System (QMS) Certificates accepted for an application for a Class 3 IVD

- TGA QMS conformity assessment certificate
- Certificates issues by a European Notified Body:
    1. under the Directive 98/79/EC
        - Annex IV Section 3 - full quality assurance certificate or other document
        - Annex VII - production quality assurance certificate or other document
    2. Under the European IVDR 2017/746
        - Annex IX Chapter I - QMS certificate
        - Annex XI (excluding section 5) - production quality assurance certificate
- Certificate issued by the Medical Device Single Audit Program (MDSAP) - encompassing the Australian regulatory requirements
- An ISO 13485:2016 certificate issued by a European Notified Body (see Note 2)
- An ISO 13485:2016 certificate issued by an accredited body that is a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum (IAF MLA). The certification body must be accredited to issues ISO 13485:2016 certificates (see Note 2).
- US FDA Pre-market Authorisation (PMA) approval

Note 1: If a false statement is made to the TGA in connection with an application for including a medical device on the ARTG, the TGA may investigate and apply relevant compliance action. This action may range from the issuing of a Warning Notice to civil or criminal penalty.

Note 2: ISO13485:2016 certificates may only be used as manufacturer evidence to support a new ARTG inclusion for an IVD medical device up until 26 May 2022. Existing ARTG entries that are supported by manufacturer evidence that is an ISO13485 certificate may continue to use this evidence up until the expiry date shown on the certificate. Thereafter, an alternate form of acceptable manufacturer evidence (//www.tga.gov.au/comparable-overseas-regulators-medical-device-applications) must be available.

Step 3.

Once the manufacturer evidence has been accepted by the TGA, you will be required to submit an application for inclusion. Guidance on submitting an application can be found on the TGA website at Medical device inclusion process (//www.tga.gov.au/book-page/step-6-submitting-application-tbs-all-classes-except-class-i-non-sterile-non-measuring-medical-device-class-1-ivd-medical-device-and-class-i-medical-deviceclass-1-ivd-medical-device-export-only). Once an application has been submitted and paid, a 41FH selection notice will be sent requesting the manufacturer's technical file for review.

Some of the information the TGA will request include:

Requirements to demonstrate compliance with the Essential Principles (EP)

Essential Principles	Information to demonstrate compliance	Requirements
EP 1, EP 2, EP 3, EP 4 and EP 6	Risk Management Report and Post-Market Data	Required

Essential Principles	Information to demonstrate compliance	Requirements
EP 4 and EP 5	Shelf-life, In-use & Transport Stability Studies	Required
EP 13 and Regulation 10.2	Device Labelling and IFU	Required
EP 14 and EP15(1)	Clinical Evidence	Detailed
EP 15(2)	Specimen Stability, Device Accuracy, Precision, Sensitivity & Specificity Studies	Detailed
EP 15(3)(4)	Calibrator & Control Information	Required
EP 15(5)(6)(7)	Usability studies and IFU suitable for self-testing	Detailed

> Additional supporting data specific for a COVID-19 self-test must be provided as specified in the COVID-19 Rapid Antigen Self-test - Supporting Data Checklist (//www.tga.gov.au/covid-19-rapid-antigen-self-tests-home-use).
>
> If you have previously accessed the supporting data checklist, please check for an updated version.

Note: The manufacturer is required to complete an Australian Declaration of Conformity (Clause 1.8, Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*) and attach the document to the application for inclusion. Templates can be found on the TGA website at Declaration of conformity templates (IVDs) (//www.tga.gov.au/form/declaration-conformity-templates-ivds).

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/Series/F2002B00237). Currently the TGA is processing COVID-19/SARS-CoV-2 assays as Class 3 IVDs.

If you intend to submit an application for inclusion on the ARTG of an IVD for the detection of SARS-CoV-2, an appropriate level 3 Global Medical Device Nomenclature (GMDN) collective term in the TGA database is "Severe acute respiratory syndrome-associated coronavirus IVDs" CT772.

Associated fees for the initial Class 3 COVID-19 test

The TGA publishes information on the current fees and charges for therapeutic goods (//www.tga.gov.au/schedule-fees-and-charges).

Regulation 5.3(1)(j) of the *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Series/F2002B00237) prescribes the kind of IVD medical device that is required to be selected for audit.

Sponsors with an application currently under review for a COVID-19 test

This section is for sponsors with an TGA application that is currently under review for another type of COVID-19 test.

What to do

For sponsors with an existing application for a COVID-19 test, please email COVIDtests@tga.gov.au (mailto:COVIDtests@tga.gov.au) directly. Please include the email subject as:

*COVID-19 Self-test - Existing Application - **DV-2021-IVA-XXXXX-1 - DA-2021-IVA-XXXXX-1 - Sponsor name***

In your email, please provide details of the existing application:

- Application ID
- Submission ID
- Sponsor name
- COVID-19 self-test device name
- An instruction to the IVD team that you wish to either:
  - Add a COVID-19 self-test as a new device to the existing application; or
  - Change the application from a COVID-19 rapid antigen point-of-care test to a COVID-19 self-test.

Please include a completed COVID-19 rapid antigen self-test - Supporting Data Checklist (//www.tga.gov.au/covid-19-rapid-antigen-self-tests-home-use) and supporting data for review.

Your application will be pushed back to include the new COVID-19 self-test as part of the existing application. The TGA will contact you directly to provide information relating to the push back.

Sponsors with an existing ARTG entry for a COVID-19 test

This section is for sponsors with an existing ARTG entry for another type of COVID-19 test, that has an assigned ARTG number.

Variation to the initial ARTG inclusion for the same kind of device

If you intend to supply an additional device that is considered to be of the same 'kind of device' as your initial COVID-19 ARTG inclusion, you may submit a variation to this ARTG entry. The additional device must meet the following definition of a kind of device.

Section 41BE of the *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Series/C2004A03952) (the Act) provides the definition of kind of device as:

41BE Kinds of medical devices

1. For the purposes of this Chapter, a medical device is taken to be of the same kind as another medical device if they:
    a. have the same sponsor; and
    b. have the same manufacturer; and
    c. have the same device nomenclature system code (see subsection (3)); and
    d. have the same medical device classification; and
    e. are the same in relation to such other characteristics as the regulations prescribe, either generally or in relation to medical devices of the kind in question.

There is an automatic condition upon the inclusion of IVD medical devices in the ARTG (Regulation 5.12 of the *Therapeutic Goods (Medical Devices) Regulations 2002*) that requires the sponsor to notify the TGA of the intention to import, supply or export a medical device of that kind. Regulation 5.12 is related to those kinds of IVD medical devices that are specified under Regulation 5.3(1)(j).

For these devices, the sponsor submits an application for variation to the relevant ARTG entry or entries. At this time, a subsequent declaration of conformity will be required.

Step-by-step instructions on how to submit a variation application are available on the TGA website (//www.tga.gov.au/book-page/fee-and-forms-varying-entries-artg).

Associated fee for a variation for a Class 3 COVID-19 test of the same kind

The TGA publishes information on the current fees and charges for therapeutic goods (//www.tga.gov.au/schedule-fees-and-charges).

Submitting supporting data

Please provide your response as electronic PDF documents via email to COVIDtests@tga.gov.au (mailto:COVIDtests@tga.gov.au).

For electronic submissions of supporting information larger than 15MB, please email eSubmissions@health.gov.au (mailto:eSubmissions@health.gov.au) and provide contact details. On receipt of these details, we will contact you to arrange registration for our temporary electronic upload facility.

The submitted electronic information must be complete, clearly tabulated, and titled. A Table of Contents must be included with the submission, clearly identifying all documents provided in the submission.

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
URL: https://www.tga.gov.au/node/940756 (https://www.tga.gov.au/node/940756)