Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

COVID-19 rapid antigen tests - information for manufacturers and sponsors

Information for manufacturers and sponsors on COVID-19 rapid antigen tests (RATs) regulatory requirements and processes.

Last updated:
11 February 2022

This is a collection of tools and resources for manufacturers and sponsors about COVID-19 rapid antigen tests.

Legal supply of COVID-19 test kits

All COVID-19 test kits must be approved for inclusion in the Australian Register of Therapeutic Goods (ARTG), in order to be legally supplied (https://www.tga.gov.au/node/289495) in Australia. One exception to this is for Class 4 in-house IVDs being used to perform donor screening under the emergency exemption (/node/289495#exemption).

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 (BICON) (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&HasChangeNotices=True&IsAEP=False).

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

Fact sheet: Importing COVID-19 rapid antigen tests (RATs) (https://www.tga.gov.au/node/288216)

This factsheet explains the differences between Australian approved rapid antigen tests and parallel imported unapproved versions, and how to determine if your RAT is a parallel import.

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 (https://www.tga.gov.au/node/287985) page.

To find approved rapid antigen test for use at the point-of-care under the supervision of a relevant health practitioner, select 'Point-of-care test' under 'show only' and sort by 'Laboratory or Point of care test'.

To find approved self-tests, select 'Self-test (home use test)' under 'show only' and sort by 'Self-test'.

Applying for TGA approval to supply a COVID-19 test in Australia

We have published information for sponsors (i.e. suppliers/importers) that wish to submit an application (https://www.tga.gov.au/node/287984) for TGA assessment for inclusion of a COVID-19 test in the Australian Register of Therapeutic Goods (ARTG). Sponsors are encouraged to review this information in conjunction with Legal supply of COVID-19 test kits (https://www.tga.gov.au/node/289495).

COVID-19 medical device application process

Sponsors are not required to request or submit a priority review as all applications in relation to COVID-19 tests are already being prioritised in assessment queues.

Warning about repackaging or relabelling COVID-19 rapid antigen tests

Retailers, distributors and others who are repackaging or relabelling COVID-19 rapid antigen tests should make sure that they are aware of their obligations under the *Therapeutic Goods Act 1989* (the Act).

Repackaging should only occur under authority of sponsor and manufacturer

Distributors and vendors should only repackage and relabel a medical device at the direction of the sponsor, and with appropriate arrangements in place with the manufacturer of the device as stated on its label.

In all instances, the person who is undertaking the repackaging or relabelling activities must:

- be authorised to perform those tasks on behalf of the manufacturer;
- have a formal quality agreement in place with the manufacturer; and
- carry out the packaging and labelling steps in a secure and controlled environment in accordance with the manufacturer's documented procedures.

Any updated packaging and labelling to be supplied with the devices must be TGA-approved versions that have undergone review as part of a regulatory submission.

If a person repackages and relabels a medical device without complying with the above requirements, this can result in the repackaged medical device legally being a different device from the one included in the Australian Register of Therapeutic Goods. As a result, the person who repackages and then on-sells that device may be breaking the law (https://www.tga.gov.au/node/287377).

Instructions for use must be provided with rapid antigen tests

Rapid antigen tests supplied in Australia are required to comply with the essential principles for safety and performance, as set out at Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Essential principle 13 requires that medical devices be supplied with instructions for their use that contain certain information about the device.

The TGA has published the PDF instructions for use that are to be supplied with COVID-19 rapid antigen self-tests that are approved in Australia (/node/288148#home-use).

A retailer, distributor or other person who supplies a COVID-19 rapid antigen test without appropriate instructions for use may be breaking the law.

Not all tests are for home use

A number of COVID-19 rapid antigen tests are included in the Australian Register of Therapeutic Goods (ARTG) on the condition that they are not to be supplied for home testing use. These are point-of-care tests that can be used outside the laboratory setting by a health practitioner, or trained staff under their supervision, to test a person for COVID-19. These tests can be displayed on the COVID-19 test kit (https://www.tga.gov.au/node/287985) page using the sort function in the table to show point of care antigen tests.

Point of care tests do not have approved instructions for use that are suitable for consumers who will be testing themselves at home. In the absence of approved instructions for use that are suitable for home use, suppliers of rapid antigen tests that are not suited for home testing run the risk of breaking the law by supplying a rapid antigen test without appropriate instructions for use.

Sponsors must ensure that they comply with the conditions under which their medical devices have been included in the Register, including any conditions relating to supply of the medical device. Sponsors who supply medical devices in breach of those conditions may be breaking the law.

TGA will investigate potential non-compliance with the Act

The Therapeutic Goods Administration will investigate any incidents that it becomes aware of where retailers of COVID-19 rapid antigen tests have repackaged these tests, often on an individual basis, for sale to the public.

The TGA will consider any allegations to determine whether the requirements of the Act are being met.

Contraventions of the Act can result in fines of up to $888,000 for individuals or $4.44 million for corporations, or civil penalties of up to $1.11 million for individuals or $11.1 million for corporations.

How to report a perceived breach or questionable practice

If you have any concerns about how COVID-19 rapid antigen self-tests are being sold in retail outlets, you can report a perceived breach or questionable practice (https://www.tga.gov.au/node/282892) to the TGA.

Manufacturing medical devices for COVID-19 including 3D printing

We have published guidance (https://www.tga.gov.au/node/289501) to assist manufacturers of medical devices and their component parts with meeting their regulatory obligations.

Topics:

COVID-19 (https://www.tga.gov.au/products/covid-19)

Medical devices (https://www.tga.gov.au/products/medical-devices)

In Vitro Diagnostic medical devices (IVDs) (https://www.tga.gov.au/vitro-diagnostic-medical-devices-ivds)