Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Meeting legal obligations for supplying COVID-19 test kits

Guidance relating to the supply of in vitro diagnostic medical devices for the detection of COVID-19/SARS-CoV-2 infections.

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Purpose

Our efforts continue to ensure Australia has COVID-19 tests available to manage the COVID-19 pandemic.

All COVID-19 test kits must be approved for inclusion in the Australian Register of Therapeutic Goods (ARTG) before they can be legally supplied in Australia.

Under the emergency exemption, Class 4 in-house IVDs can be used for donor screening.

> This is current advice relating to the supply of COVID-19 tests. Changes in COVID-19 could change this advice.

Legislation

Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021

Therapeutic Goods (Medical Devices) Regulations 2002

Therapeutic Goods Act 1989

Applications for COVID-19 tests

We are no longer prioritising COVID-19 test applications.

See Applying for TGA assessment of a COVID-19 test for inclusion in the ARTG.

Conditions imposed on all approved COVID-19 tests

All COVID-19 tests that are included in the ARTG, based on an expedited assessment process and/or limited validation data, have been subject to additional non-standard conditions.

Post-market surveillance activities continue to be informed by these conditions.

Additional conditions

Additional conditions are being imposed on the supply of COVID-19 serology-based tests (i.e., serological rapid screening tests) and rapid antigen tests for use at the point-of-care and for self-testing to ensure the tests are used and interpreted appropriately. Point-of-care tests require the involvement of a suitably trained health practitioner. A rapid antigen self-test can be done by without the involvement of a health practitioner.

See Conditions on all COVID-19 tests approved for ARTG inclusion.

ARTG approved COVID-19 test kits

In vitro diagnostic (IVD) test sponsors can apply for inclusion in the ARTG. Once approved, the test can be supplied in Australia.

All COVID-19 test kits approved by the TGA for inclusion in the ARTG are listed on the COVID-19 test kit page. See COVID-19 rapid antigen self-tests included in the ARTG for more.

This device can only be supplied by an approved sponsor of a COVID-19 test or a person acting on their behalf.

All sponsors of COVID-19 tests included in the ARTG have ongoing responsibilities under:

- the *Therapeutic Goods Act 1989* (the Act),
- *Therapeutic Goods (Medical Devices) Regulations 2002* and
- *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (the Advertising Code), including conditions that apply automatically to all ARTG entries.

We encourage all sponsors of COVID-19 tests to review this information.

See how to seek medical attention if you are sick and think you have symptoms of COVID-19.

COVID-19 test kits and what to do if you get a positive result may vary by state.

Information for laboratories

COVID-19 Class 1-3 in-house IVDs

Class 1-3 in-house IVD medical devices used for COVID-19 diagnostic testing can be developed by a laboratory under the regulatory requirements for in-house IVDs. Laboratories can make in-house IVDs by adapting Research Use Only Products (RUO) tests or by developing their own assays to test for COVID-19 infections. Class 1-3 in-house IVDs do not require inclusion in the ARTG.

Regulatory requirements for labs that make and use Class 1-3 IVDs include:

- be NATA accredited to ISO 15189 (for a medical testing laboratory); and
- comply with the requirements of the NPAAC standard, *Requirements for the development and use of in-house in vitro diagnostic medical devices*; and
- submit a notification to us by 1 July of that financial year.

Use of alternative COVID-19 sample types

Use of alternative specimen types, such as self-collected saliva samples (i.e., sample types not validated by the manufacturer) for COVID-19 diagnostic testing requires validation by the laboratory as a Class 1-3 in-house IVD.

For information on in-house IVDs go to the regulatory requirements.

Contact us

For more information about COVID-19 tests:

Email IVDs@tga.gov.au

Telephone **1800 141 144**

For general COVID-19 enquiries contact the National Coronavirus Helpline on:

Telephone **1800 020 080** (available 24 hours a day, seven days a week)

Topics: Advertising COVID-19 Regulatory compliance Import and export In Vitro Diagnostic medical devices (IVDs)

Featured in: COVID

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