



### Who can import rapid antigen tests to supply in Australia?

Only the approved supplier (sponsor), as entered on the [Australia Register of Therapeutic Goods](#) (ARTG), or their agent can import rapid antigen tests (RATs) into Australia for commercial supply.

Any RATs imported for commercial supply must be the version manufactured and approved for the Australian market and not a [parallel import](#). The RATs must be on the ARTG, under the name of the supplier, prior to importation.

RATs not entered in the ARTG are subject to biosecurity controls administered by the Department of Agriculture, Water and the Environment.

Unless an import can be demonstrated as being for personal-use-only, any import of unapproved RATs will not meet the [BICON - Import Conditions](#) and a biosecurity import permit will be required. Imports not meeting these requirements will be assessed at the border and may not reach their destination.



Do not import RATs unless you are:

- the Australian approved supplier (sponsor) or
- their agent.

### What is a parallel import?

Many therapeutic goods, including RATs, are available both in Australia and overseas.

There may be different packs or labels on a version that is approved for supply in Australia, compared to those versions for supply in other countries. Differences ensure compliance with

the therapeutic goods laws in the country where the goods are intended to be sold.

Parallel import occurs when a legitimate version of an overseas product is imported with the intention of being sold in the Australian marketplace. While these goods may be authentic and manufactured by the company indicated on the packaging, they are not the version of the product assessed for the Australian market and entered in the ARTG.

Parallel imports do not necessarily meet the same quality and safety standards that the Australian versions do and have not been assessed by the TGA. Parallel imports are unapproved goods and should not be imported into Australia for commercial supply.

### How do I know if my good is a parallel import?

If your business intends to supply a therapeutic good, such as RATs, to consumers or businesses in Australia, you should obtain those goods via formal manufacturer distribution channels.

Where you obtain genuine products without authorisation from the manufacturer, you may be purchasing a parallel import. If any of the following apply to your product, it may be a parallel import:

- it has been purchased from a supplier other than the manufacturer or its authorised distributor
- it has not been assessed by the TGA for the Australian market

- the price you intend to sell it for is cheaper than a consumer would ordinarily expect to pay for the product in Australia
- the packaging and instructions for use are not in English
- there are no Australian sponsor details on the package.

### What RATs are included on the ARTG?

All COVID-19 test kits approved by the TGA for inclusion in the ARTG are listed on the [COVID-19 test kit](#) page.

### Responsibilities when importing RATs

Where an Australian business imports RATs for subsequent supply, they must have a reasonable expectation that the RAT will ultimately be supplied to a consumer.

The safest way for industry to obtain RATs for supply in the Australian market is to obtain them via formal manufacturer distribution channels.

You must always ensure that any RATs you are importing comply with Australian therapeutic goods legislation including:

- the [Therapeutic Goods Act 1989](#)
- the packaging and labelling requirements in TGO 110
- the [Therapeutic Goods Regulations 1990](#)
- the [Therapeutic Goods \(Therapeutic Goods Advertising Code\) Instrument 2021](#).

### What are the consequences of importing unapproved RATs?

#### Loss of product

Under instruction of the TGA, the Australian Border Force can seize and destroy unlawful imports of therapeutic goods, including RATs.

#### Fines or court action

The TGA investigates unlawful import, supply and advertising of RATs in Australia and encourages compliance with Australian laws by providing education and guidance in the first instance. Failing to adhere to the Australian rules can attract significant penalties.

For repeated and deliberate non-compliance, the TGA takes escalated regulatory action which can include injunctions, infringement notices, civil court proceedings and criminal prosecution.

### How do I apply for TGA approval to supply RATs in Australia?

We have published information for sponsors (i.e. suppliers/importers) that wish to [submit an application](#) for TGA assessment for inclusion of a COVID-19 test in the ARTG.

You are encouraged to review this information in conjunction with the [Legal supply of COVID-19 test kits](#).

### Further information

- Find out [more about being a sponsor](#) on our website.
- [COVID-19 rapid antigen tests - information for manufacturers and sponsors](#)
- [Buying parallel imports | ACCC](#)
- [Selling parallel imports | ACCC](#)
- [Advertising enforcement and outcomes](#)
- [BICON - Import Conditions - Conditions \(agriculture.gov.au\)](#)
- [Media releases & statements](#)



Australian Government

Department of Health  
Therapeutic Goods Administration

## Importing COVID-19 rapid antigen tests (RATs)

### Examples – comparison of Australian vs overseas products (parallel imports)

#### Example 1

Image of Australian approved version



Sponsored by:  
AM Diagnostics Pty Ltd  
Unit 8, 25 Wicks Street, Bayswater, WESTERN AUSTRALIA 6053  
PH: 1800 472 743 www.amdiagnostics.com.au

 **Hangzhou AllTest Biotech Co.,Ltd.**  
#650, Yinhai Street,  
Hangzhou Economic & Technological Development Area,  
Hangzhou, 310016 P.R. China  
Web: www.alltests.com.cn Email: info@alltests.com.cn



CE 1434 IVD

PLEASE SCAN THE QR CODE  
FOR MORE INFORMATION REGARDING THE TEST

 **MedNet GmbH**  
Birkstrasse 10 48163 Muenster Germany  
**Hangzhou AllTest Biotech Co.,Ltd.**  
#650, Yinhai Street,  
Hangzhou Economic & Technological Development Area,  
Hangzhou, 310016 P.R. China  
Web: www.alltests.com.cn Email: info@alltests.com.cn

Authorized Representative / Product Distributed by:  
**Global Science Sdn Bhd**  
Unit 816, Level 8, Block D, Kelana Square,  
No 17, Jalan SS7/26, Kelana Jaya,  
47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia.  
Tel no: 603-7804 3522  
Fax: 603-7804 4822  
Email: support@globalscience.my

## Example 2

Parallel import version: No Australian distributor or Sponsor listed on the test kit.

