



Australian Government
Department of Health
Therapeutic Goods Administration

COVID-19 rapid antigen self-tests that are approved in Australia

15 October 2021

The TGA has approved the following COVID-19 self-tests (home use tests) for supply in Australia from 1 November 2021.

Please refer to the instructions on how to use each test (that are provided in the table below) for further information on what sample types the test can be used with (e.g. nasal swab or saliva).

COVID-19 self-tests (home use) approved by TGA

*Clicking on the name of the test will link to the instructions on how to use it.

Name of self-test* and how to use the test	Australian Sponsor (supplier)	Manufacturer	ARTG	Date Approved
<u>All Test COVID-19 Antigen Rapid Test (Oral Fluid) Self-Test (ICOV-802H) (pdf,366kb)</u> <u>(//www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-oral-fluid-01.pdf)</u>	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd	376310	13 October 2021
<u>All Test SARS-CoV-2 Antigen Rapid Test (Nasal Swab) (ICOV-502H) Self-Test (pdf,649kb)</u> <u>(//www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-nasal-swab.pdf)</u>	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd	376310	13 October 2021

Name of self-test* and how to use the test	Australian Sponsor (supplier)	Manufacturer	ARTG	Date Approved
<p><u>My Covid Test Antigen Rapid Test (Oral Fluid) (ICOV-802H) Self-Test (pdf,366kb)</u> <u>(//www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-oral-fluid-02.pdf)</u></p>	AM Diagnostics	Hangzhou Alltest Biotech Co Ltd	376310	13 October 2021
<p><u>RightSign COVID-19 Antigen Rapid Test Cassette (Nasal Swab) (pdf,1.06Mb)</u> <u>(//www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-ifu-333344.pdf)</u></p>	Medsupply Australia Pty Ltd	Hangzhou Biotest Biotech Co Ltd (China)	333344	15 October 2021
<p><u>SARS-CoV-2 Antigen Self Test Nasal (pdf,619kb)</u> <u>(//www.tga.gov.au/sites/default/files/covid-19-rapid-antigen-self-tests-are-approved-australia-ifu-352250.pdf)</u></p>	Roche Diagnostics Australia Pty Limited	SD Biosensor Inc (Korea - Republic of)	352250	15 October 2021

Category: Medical devices/IVDs

Tags: medical devices, COVID-19 tests, rapid antigen testing, businesses, self-tests, home use

URL: <https://www.tga.gov.au/node/940763> (<https://www.tga.gov.au/node/940763>)