

COVID-19 Antigen Rapid Test (point of care)

For Healthcare Professionals Only



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CONTENT



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Product Information (25 tests/box)

◆ Components

Extraction Tube &
Dropper Tip (x25)



Extraction
Reagent (x25)



Sterilized Swab
(x25)



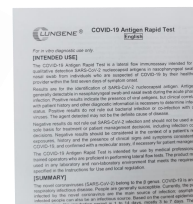
Test Cassette
(x25)



Work Station
(x1)



Package Insert
(x1)



COVID-19 Antigen Rapid Test (Export Packing Carton Information)

1250 tests/carton

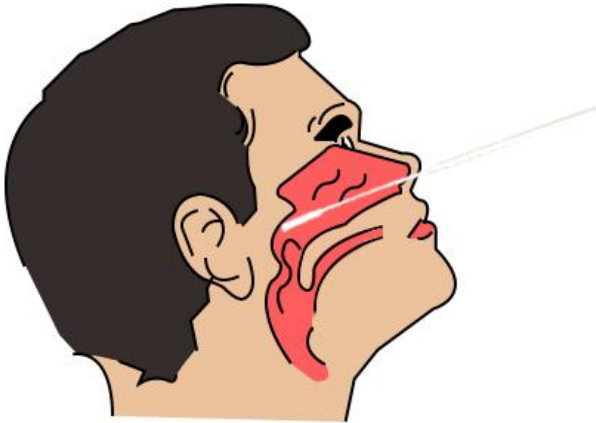
Packing Size: 64cm*34cm*55cm

Estimated Gross Weight: 17.5kg

Sample Collection



- **Nasopharyngeal Swab**

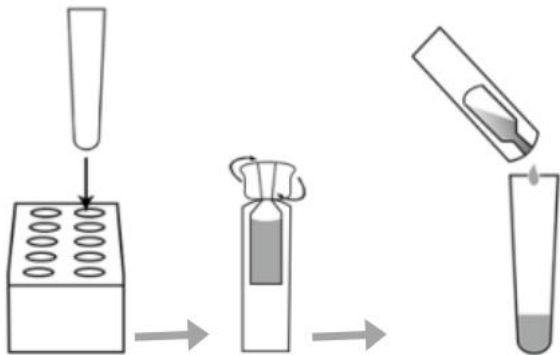


- **Nasal Swab**

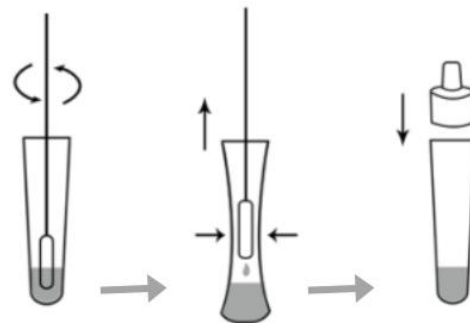


Test Procedure

Add the extraction reagent into the extraction tube.

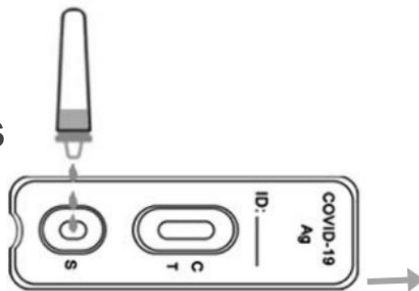


Roll the swab at least 5 times.
Leave the swab in the extraction tube for 1 minute.



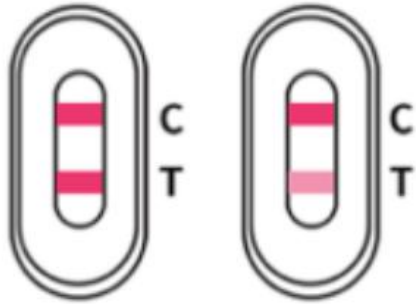
1 2 3

3 drops



Interpret the test results at 15 minutes. Don't read results after 20 minutes.

Read Results



Positive



Negative



Invalid

TGA Listing Info

Clungene Covid-19 Antigen Rapid Test

Listed with TGA under ARTG No. 333341



COVID-19 test kits included in the ARTG for legal supply in Australia

10 January 2022

The TGA has approved the following tests for inclusion in the Australian Register of Therapeutic Goods (ARTG).

Please note:

- Conditions have been imposed on the supply of COVID-19 rapid antigen point-of-care tests, [COVID-19 rapid antigen self-tests \(home use tests\)](#) and [COVID-19 serology point-of-care tests](#). Further information can be found at: [Legal supply of COVID-19 test kits](#).
- For guidance on understanding the key considerations for establishing COVID-19 rapid antigen point-of-care testing in your workplace, see [COVID-19 Rapid Antigen Point-of-Care Tests – Guidance for implementation and checklist for businesses](#).
- The Peter Doherty Institute for Infection and Immunity (the Doherty Institute) has been engaged by the Department of Health to assist with the [post-market validation](#) of new COVID-19 rapid antibody tests to inform their best use.
- The TGA is undertaking a post-market review on the [ability of COVID-19 tests to detect emerging genetic variants of SARS-CoV-2](#) for all COVID tests in the ARTG.
- COVID-19 tests suspended from the ARTG are published on the TGA website – [Medical devices and IVDs: Suspension from the ARTG](#).

For more information please contact us at COVIDtests@tga.gov.au or 1800 141 144.

Only the approved Sponsor (i.e. importer) listed in the table below, or a person acting on their behalf (i.e. the person has a distribution arrangement with the sponsor), can supply the device.

Please refer to the instructions for use for each test to determine intended specimen types.

COVID-19 test kits included on the ARTG for legal supply in Australia

Displaying 1 - 164 of 164

Show only

- Any -

Sort by

Manufacturer

Manufacturer: Hangzhou Clungene Biotech Co Ltd
Name of test: Clungene Covid-19 Antigen Rapid Test
Australian sponsor: APAC Security Pty Ltd
Date approved for supply: 7 Jan 2022

Point-of-care test*
Antigen Test

Clongene is a high-tech enterprise specialized in biological raw materials and in vitro diagnostic products. Founded in 2004, Clongene is equipped with state-of-the-art ISO 13485:2016 accredited-China GMP compliant R&D and manufacturing facilities covering 19,000 square meters in Hangzhou, China. Our products have obtained CE certificates, FSC certificates and US FDA 510(k) clearances.

Clongene keeps growing and pays much attention to the R&D of raw materials and in vitro diagnostic products, in order to bring more value to our clients. Our technology platforms including colloidal gold immunoassay (CGIA), enzyme-linked immunosorbent assay (ELISA), chemiluminescence immunoassay (CLIA), fluorescence immunoassay (FIA) and molecular diagnosis (RT-PCR). We also provide high quality biological raw materials including antigen, antibody and enzyme products.

