

SARS-CoV-2 Rapid Antigen Test

Enables fast decision-making to help limit further spread

The SARS-CoV-2 Rapid Antigen Test and SARS-CoV-2 Rapid Antigen Test Nasal allow for fast decentralised testing at the point of care, with results available within 15 to 30 minutes. No instrument or specialised equipment is required. They are useful in expanding testing availability into diverse settings outside the laboratory, including rural/remote and low infrastructure areas.¹

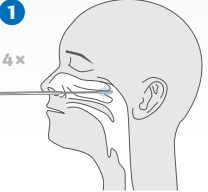
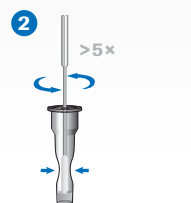
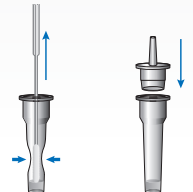
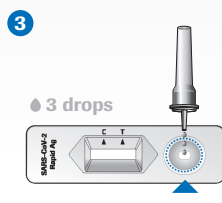
These rapid antigen tests are useful for medical or healthcare practitioners to test individuals suspected of COVID-19, or with known or suspected exposure to SARS-CoV-2. They provide a rapid and economical means to help decide if an individual may need to be quarantined/isolated, or whether further testing is needed.²

Main benefits

- » **No analyser** required
- » **Fast results** with a 15 minute turn around time
- » **Prefilled reagents** to ensure simple ease of use, minimal handling steps, and reduced risk of manual errors
- » **Virus inactivation** is achieved in the buffer after 2 minutes
- » **Sample options:** test sample directly from patient; and for NP test, a sample already contained in viral or universal transport media
- » **Storage:** test kits can be stored at room temperature

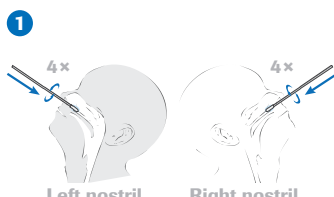
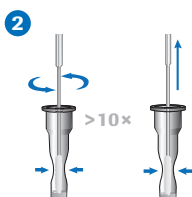
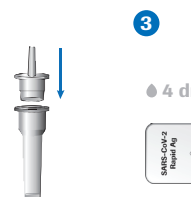
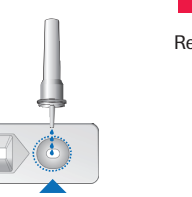
Getting fast answers is just a few steps away

Performing the Roche SARS-CoV-2 Rapid Antigen Test

-  1. Collect the nasopharyngeal sample with the supplied swab.
-  2. Insert the swab into an extraction buffer tube and mix.
-  3. Remove the swab while squeezing the sides of the tube and replace cap.
-  4. Apply 3 drops of extracted sample to the test device.

15–30 min

Performing the Roche SARS-CoV-2 Rapid Antigen Test Nasal

-  1. Collect the nasal sample with the supplied swab from each nostril.
-  2. Insert the swab into an extraction buffer tube and mix.
-  3. Remove the swab while squeezing the sides of the tube and replace cap.
-  4. Apply 4 drops of extracted sample to the test device.

Risk of incorrect results. Do not read the test result after 30 min.

Read the test result at 15 - 30 min.

Nasal sampling can help reduce overall patient discomfort, particularly in sensitive individuals such as children, elderly people and/or people with disabilities.

Delivering reliable results at the point of care^{3,4,5}

SARS-CoV-2 Rapid Antigen Test

Sensitivity	95.5% (Ct value \leq 30; 95% CI: 91.8% - 97.8%)
Specificity	99.2% (95% CI: 98.2% - 99.7%)

SARS-CoV-2 Rapid Antigen Test Nasal

Sensitivity	82.7 % (95 % CI: 75.6 % - 88.4 %)
Specificity	99.1 % (95 % CI: 97.9 % - 99.7 %)

Reference:

1. Subject to the current TGA conditions on inclusion specifically for rapid antigen point-of-care tests. (<https://www.tga.gov.au/applying-tga-assessment-covid-19-test-inclusion-artg>)
2. Refer to the current instructions for use for full information.
3. Compared to an FDA EUA authorised laboratory based real time reverse transcription PCR test.
4. SARS-CoV-2 Rapid Antigen Test Product Information AU V3.0.
5. SARS-CoV-2 Rapid Antigen Test Nasal Product Information AU V2.0.

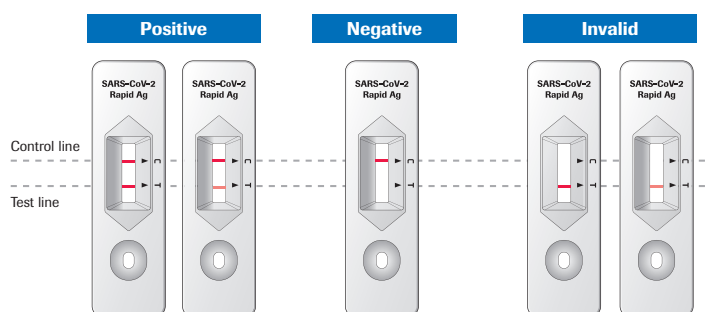
Assay Characteristics

Test type	Qualitative - rapid chromatographic immunoassay
Sample type	<ul style="list-style-type: none"> ▪ Direct collection from patient ▪ Nasopharyngeal: Sample contained in VTM/UTM
Target antigen	Nucleocapsid (N)
Time to result	15 minutes
Time to read result	Between 15 & 30 minutes
Storage temperature	Store the kit at 2-30°C / 36-86°F out of direct sunlight. Do not freeze.
Stability	NP: Up to 1 hr (15-25°C) or 4 hr (2-8°C) / Nasal: Up to 4 hr (15-25°C or 2-8°C)
Registration	Included on ARTG 352250

Understanding the results when you need to know



C Control, test is valid
 T Antigens specific to SARS-CoV-2 detected



In case of a positive result, a coloured test line T appears in the lower section of the result window.

In case of a negative result, only the control line C appears.

If no control line C is visible, the test is always invalid.

Test Description	Quantity Per Kit
SARS-CoV-2 Rapid Antigen Test	25
SARS-CoV-2 Rapid Antigen Control Kit	10 sets of positive and negative
SARS-CoV-2 Rapid Antigen Test Nasal*	25
SARS-CoV-2 Antigen Control Swab	10 each of positive and negative controls

*1 x positive and negative QC included in the SARS-CoV-2 Rapid Antigen Test Nasal kit

Catalogue Number
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09338322190
09365397043
09396276043

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Roche Diagnostics Australia Pty Limited
2 Julius Avenue
North Ryde NSW 2113 Australia
ABN 29 003 001 205
Phone: 02 9860 2222

E-mail: australia.dia_cardiology@roche.com.au

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