# SARS-CoV-2 Rapid Antigen Test

*Testing ready to go when you need to know*

SARS-CoV-2 Rapid Antigen Test allows for decentralised testing at the point of care and assists in expanding the range and volume of virus testing into diverse settings, particularly if laboratory testing is limited or unavailable. In addition, the SARS-CoV-2 Rapid Antigen Test is an instrument-free test, enabling testing in many settings including rural and low-infrastructure areas.

The SARS-CoV-2 Rapid Antigen Test enables fast decision making to determine if patients need to be put in quarantine, thus reducing the risk of further spreading of the virus. It also allows for screening of individuals after confirmed exposure to a SARS-CoV-2 infected person or individuals that are high risk for exposure such as health care workers.

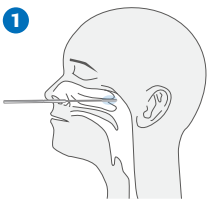
## Main benefits

- **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 the patient or to test sample already contained in viral or universal transport media
- **Storage:** test kits can be at room temperature

## Getting fast answers is just a few steps away

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

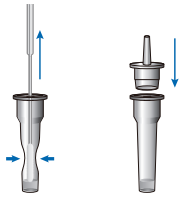
1



Collect the nasopharyngeal sample with the supplied swab.

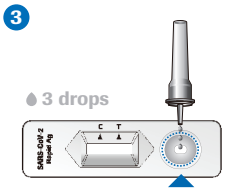
2


Insert the swab into an extraction buffer tube and mix.



Remove the swab while squeezing the sides of the tube and replace cap.

3




Apply 3 drops of extracted sample to the test device.

4

**15 – 30 min**

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

Read the test result at 15 - 30 min.

# Delivering reliable results at the point of care

## Clinical Performance

Clinical performance was determined from a sample cohort of 975 samples across two prospective studies. The overall relative sensitivity was 95.5% (Ct value ≤ 30) and specificity 99.2%.[1,2]

## SARS-CoV-2 Rapid Antigen Test

| | |
|---|---|
| **Sensitivity** | 95.5% (Ct value ≤ 30; 95% CI: 91.8% - 97.8%) |
| **Specificity** | 99.2% (95% CI: 98.2% - 99.7%) |

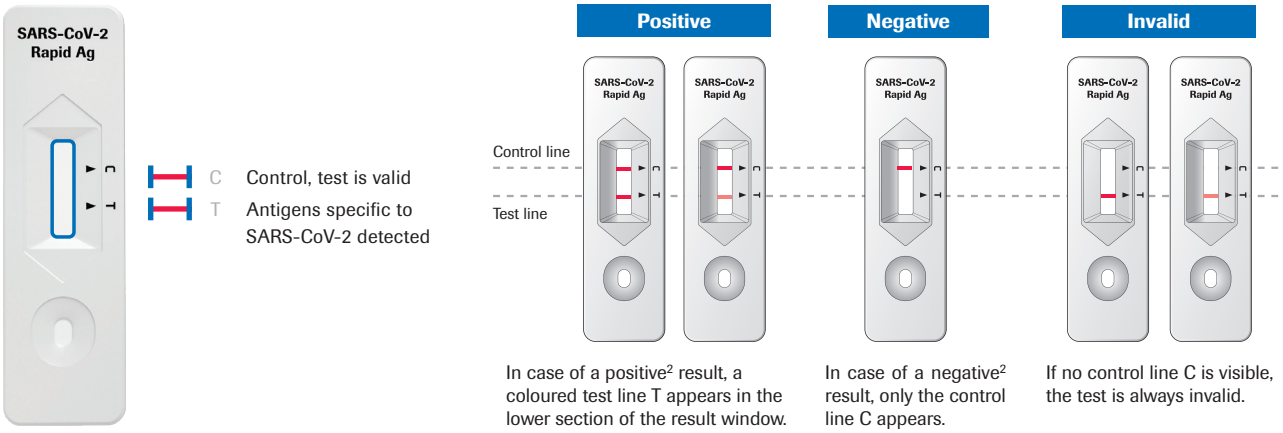
Reference:


1. Compared to an FDA EUA authorised laboratory based real time reverse transcription PCR test.
2. SARS-CoV-2 Rapid Antigen Test Product Information AU V1.0


## Assay Characteristics

| | |
|---|---|
| **Test type** | Qualitative - rapid chromatographic immunoassay |
| **Sample type** | Nasopharyngeal<br>▪ Direct collection from patient<br>▪ Sample contained in VTM/UTM |
| **Target antigen** | Nucleocapsid (N) |
| **Time to result** | 15 minutes |
| **Time to read result** | From 15 - 30 minutes |
| **Storage temperature** | 2 - 30°C |
| **Stability (test, opened pouch)** | 1 hour once the test has been opened |
| **Registration** | Included on ARTG 352250 |

# Understanding the results when you need to know




| Test Description | Quantity Per Kit | Catalogue Number |
|---|---|---|
| SARS-CoV-2 Rapid Antigen Test | 25 | 09327592190 |
| SARS-CoV-2 Rapid Antigen Control Kit | 10 sets of positive and negative | 09338322190 |



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COVID-19 rapid antigen point of care tests should be conducted by a medical practitioner or a registered/enrolled nurse who can provide an individual with appropriate advice and treatment.