SARS-CoV-2 Rapid Antigen Test
Quick Factsheet

Sensitivity:
86.2–90.0 %

Specificity:
97.9–99.3 %
(Patients with onset of clinical symptoms within 5 days)

Kit components

- Test device (individually in a foil pouch with desiccant)
- Extraction buffer tube
- Nozzle cap
- Sterile swab
- Film (can be attached to the test device when performing outdoor testing)
- Instructions for use & Quick Reference Guide

Each kit contains 25 individually packaged, ready-to-use tests.

Ordering information

Test	Quantity per kit	Order No	Cat No
SARS-CoV-2 Rapid Antigen Test English Version	25	09327592190	99COV30D-EN01

Assay characteristics

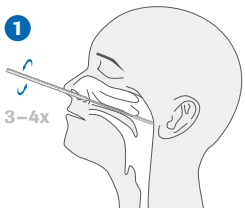
Test description	The SARS-CoV-2 Rapid Antigen Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleoprotein antigen in nasopharyngeal (NP) swabs from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of symptoms. The SARS-CoV-2 Rapid Antigen Test is intended for use by trained laboratory personnel and healthcare professionals for laboratory use or point of care testing. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. This assay is not intended to be used for diagnostics. This assay is not intended for home testing (or self-testing).
Test type	Qualitative
Sample type	Nasopharyngeal swab
Target antigen	Nucleocapsid (N)
Time to result	15 minutes (Readout window 15 – 30 minutes)
Storage temperature	2 – 30 °C / 36 – 86 °F
Stability (test, opened pouch)	1 hour once the test has been opened
Control	Positive and negative controls are optional components and can be ordered separately

Clinical Performance

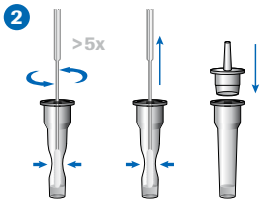
The performance of SARS-CoV-2 Rapid Antigen Test with prospectively collected nasopharyngeal swab clinical samples was evaluated at Three sites. Analysis of the sensitivity and specificity was performed using samples collected from patients with an onset of clinical symptoms of ≤5 days and included 89 SARS-CoV-2 positive clinical specimens and 1017 SARS-CoV-2 negative clinical specimens.

	Germany	**Brazil**
Sensitivity days ≤ 5, N	86.2 % (69.4, 94.5); 29	90.0 % (79.9, 95.3); 60
Specificity days ≤ 5, N	99.3 % (98.4, 99.7); 824	97.9% (94.8, 99.2); 193

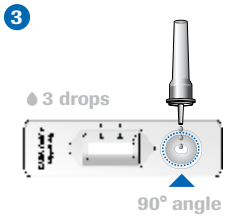
Performing a test



Taking a nasopharyngeal sample**



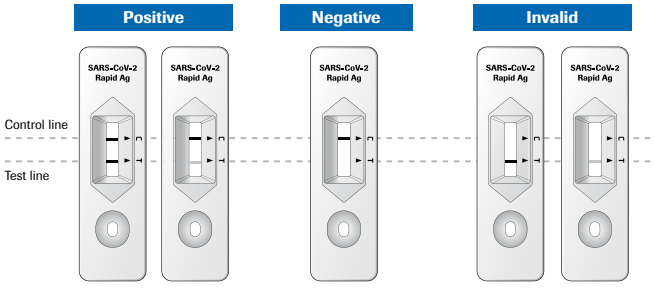
Preparing a sample



Performing a test

Read the result

Results interpretation



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**When collecting a combined NP sample be sure to follow the procedures described in the Instructions for Use.