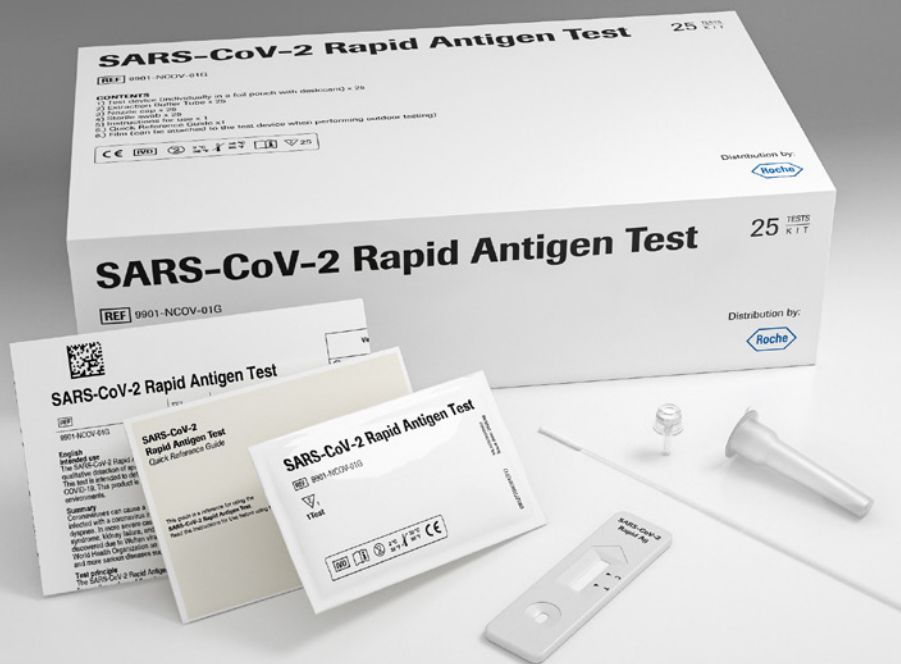


SARS-CoV-2 Rapid Antigen Test

Quick factsheet



Sensitivity:
96.52%*

Specificity:
99.68%*

Kit components

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

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 rapid chromatographic immunoassay for the qualitative detection of specific antigens of SARS-CoV-2 present in the human nasopharynx. This test is intended to detect antigen from the SARS-CoV-2 virus in individuals suspected of COVID-19. The test is intended for professional use only.
Test type	Qualitative
Sample type	Nasopharyngeal swap
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 test was found to have a sensitivity of 96.52% and a specificity of 99.68%. This was determined from a sample cohort of 426 samples from two independent study centers.*

SARS-CoV-2 Rapid Antigen Test	PCR		
	Positive	Negative	Total
Positive	111	1	112
Negative	4	310	314
Total	115	311	426
Sensitivity	96.52% (111/115, 95% CI 91.33 – 99.04%)		
Specificity	99.68% (310/311, 95% CI 98.22 – 99.99%)		

Performing a test

1

Taking a sample

2

Preparing a sample

3

Performing a test

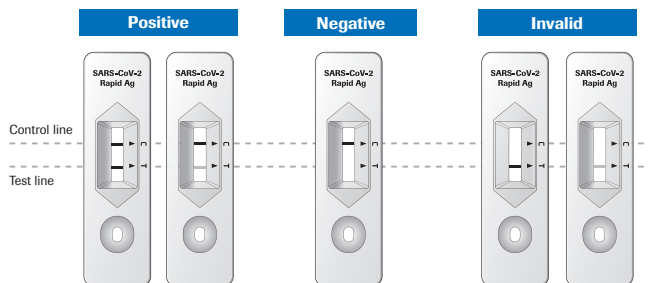
4

15 – 30 min

Reading the result

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

Results interpretation



*Reference: SARS-CoV-2 Rapid Antigen Test Product Information V01

© 2020 Roche Diagnostics Limited. All rights reserved.

Roche Diagnostics Limited
 Charles Avenue, Burgess Hill, West Sussex, RH15 9RY.
 Company Registration Number: 571546.
 Date of Preparation: September 2020. Material Number: MC-UK-00660

For healthcare professional use only in the UK and Ireland. Not for distribution.
www.roche.com