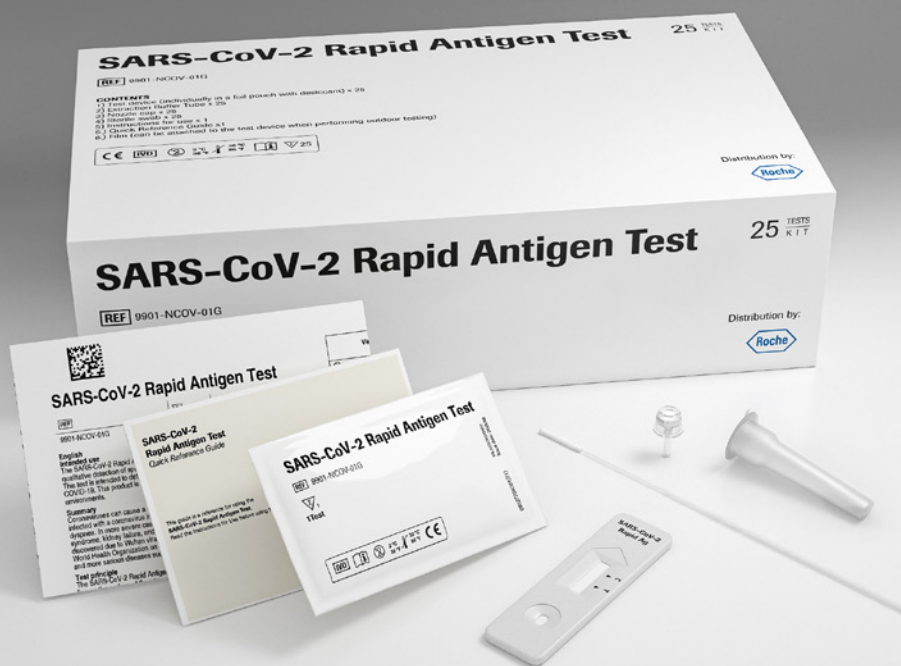


SARS-CoV-2 Rapid Antigen Test

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 & 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

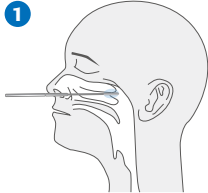
Clinical Performance

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%)		

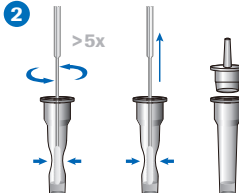
Performing a test

1



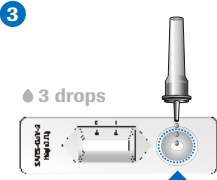
Taking a sample

2




Preparing a sample

3



Performing a test

4

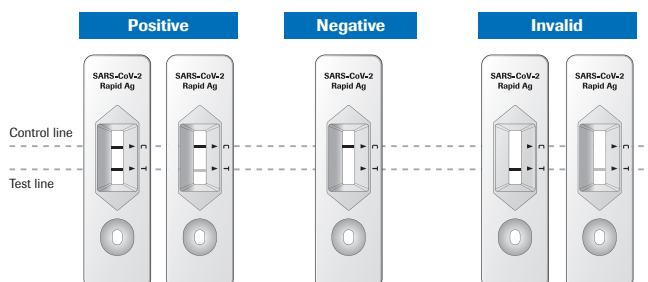


15 – 30 min

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

Read the result

Results interpretation



References:

SARS-CoV-2 Rapid Antigen Test Product Information V01

Distributed by:

Roche Diagnostics (PTY) Ltd.

Building E

Hertford Office Park

90 Bekker Road

Vorna Valley

Midrand

South Africa

MC-ZA 00248

10/2020