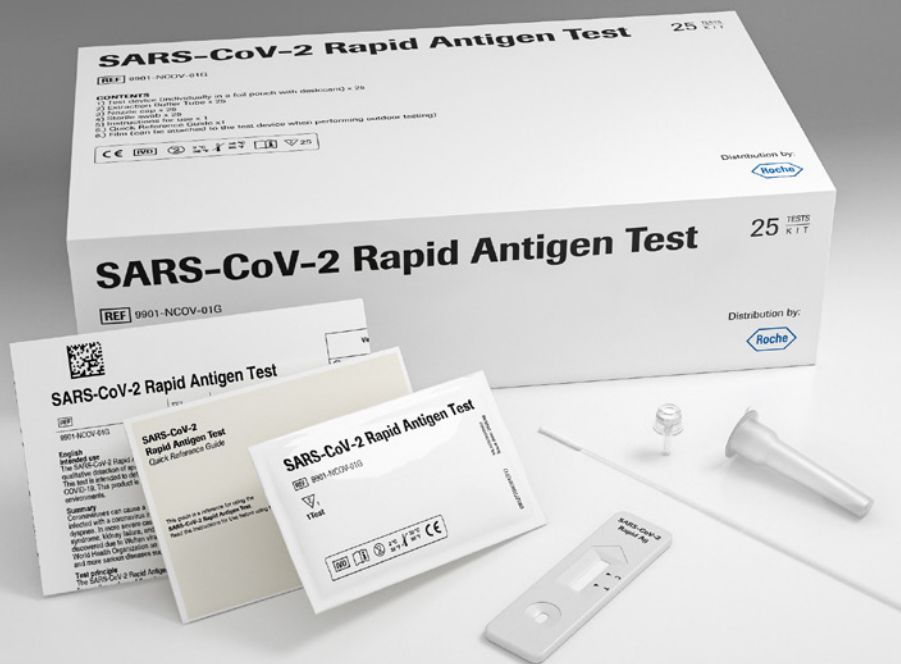


SARS-CoV-2 Rapid Antigen Test

Quick factsheet



Sensitivity:
96.52%*

Specificity:
99.68%*

Kit components

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

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

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

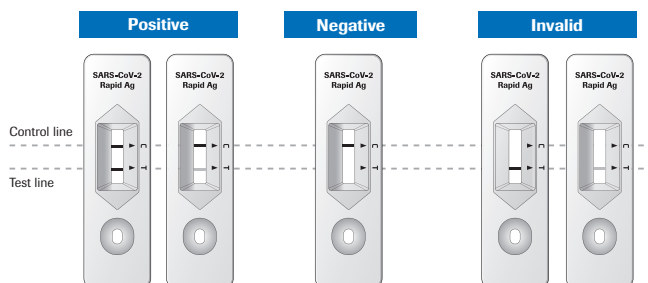
4

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