SARS-CoV-2 Rapid Antigen Test Nasal

Convenient sampling, quick results

Introducing the SARS-CoV-2 Rapid Antigen Test Nasal

Nasal swab sample collection

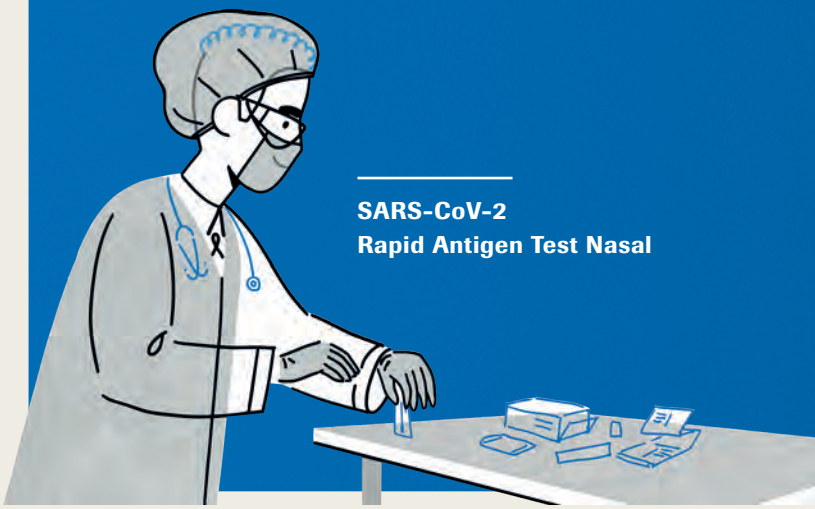
90.6 %
(Ct ≤ 30)

Sensitivity[1]

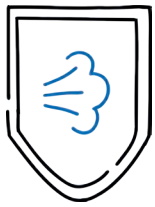
98.6 %

Specificity[1]

Convenient sampling, quick results



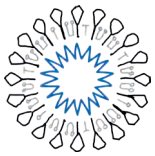
SARS-CoV-2 Rapid Antigen Test Nasal



Decreased risk of exposure for healthcare professionals

Results after 15 min

Pre-filled tubes



Target antigen
Nucleocapsid (N)

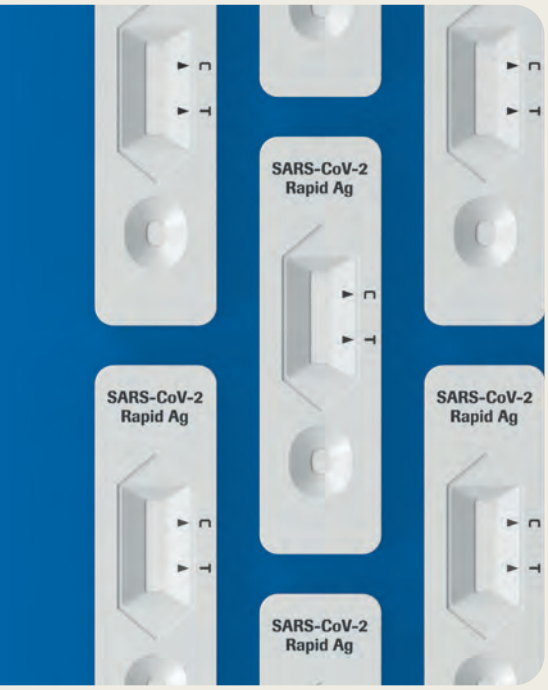
Test stability
1 hour after opened pouch

Self-collection possible
under supervision of a healthcare worker

Less invasive point-of-care testing with increased protection for healthcare professionals

Key benefit

No instruments needed



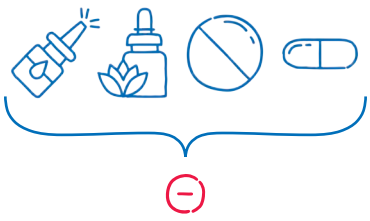
Shelf life: 24 months after manufacturing date*

1× positive and negative QC included in the kit

(36-86 °F)

Storage temperature

Cross-reactivity



54 human-pathogenic specimens tested negative for cross-reactivity.**
15 potential substances tested negative for interference.

Test description

The SARS-CoV-2 Rapid Antigen Test Nasal is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigen present in human nasal samples.

This assay is intended to detect antigen from SARS-CoV-2 in individuals suspected of COVID-19 or with known or suspected exposure to SARS-CoV-2. The test is intended for professional use in laboratory and point-of-care environments, or self-collection under the supervision of a healthcare worker.

*Shelf life may be reduced for lots produced before April 2021.

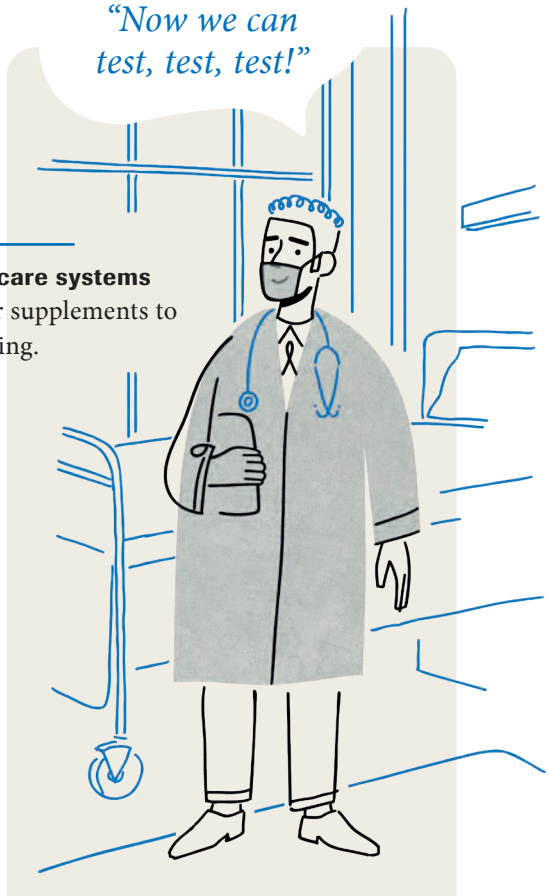
**Cross-reactivity is possible with human coronavirus HKU1 (31.6 % homology), *Pneumocystis jirovecii* (PJP) (12.3 % homology) and *Mycobacterium tuberculosis* (TB) (13.0 % homology).

The SARS-CoV-2 Rapid Antigen Test Nasal – at your service

Individuals at risk of exposure
Easier routine testing in point-of-care settings.

Symptomatic patients
Quick results enable fast decision making on self-isolation.

Healthcare professionals
Collection of nasal specimens can decrease risk of exposure.



Healthcare systems
Further supplements to lab testing.

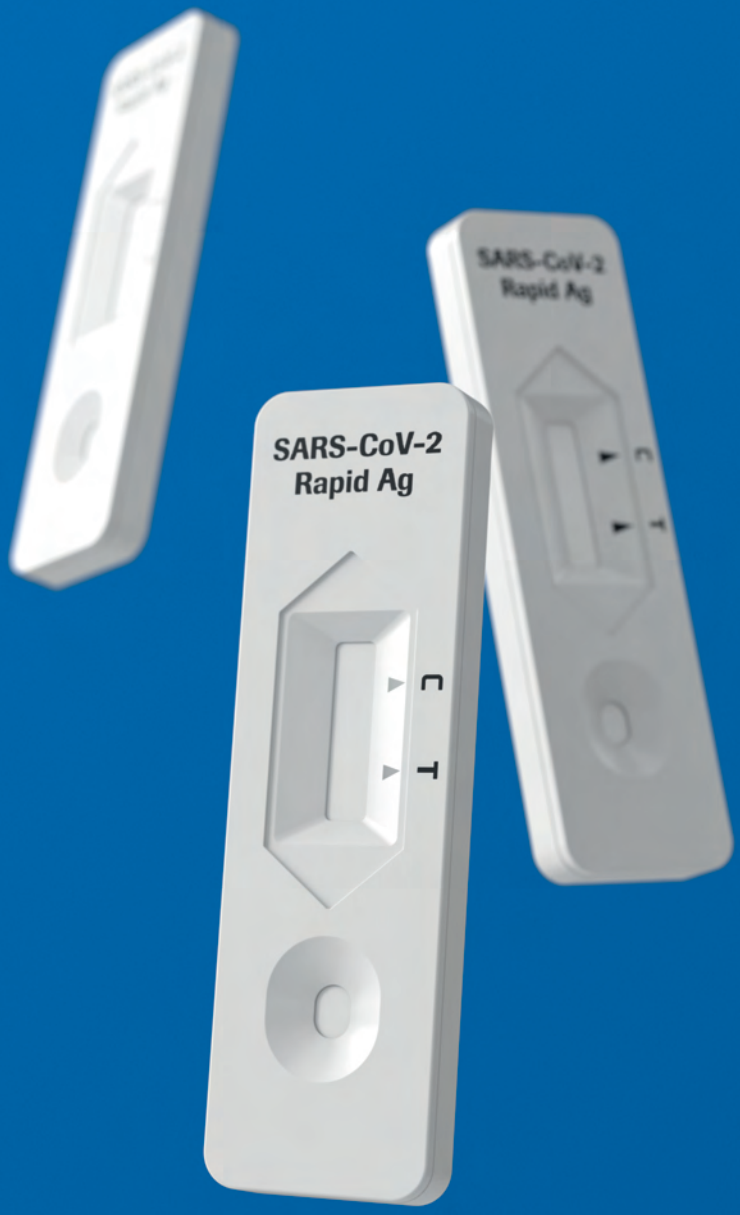
The SARS-CoV-2 Rapid Antigen Test Nasal enables…

…fast decision-making to help prevent further spreading.

The SARS-CoV-2 Rapid Antigen Test Nasal provides rapid results for fast decision-making at the point of care.

Decision-making on self-isolation for symptomatic patients or asymptomatic individuals with a known or suspected exposure to SARS-CoV-2 can help reduce the risk of passing on the virus. Infected patients who go into quarantine help to protect their contacts such as family, friends and co-workers.

As an additional option, rapid point-of-care tests can fill the gap if lab capacities are challenged by an exceptionally high demand for PCR testing. Point-of-care tests can also facilitate testing when traveling to a test location is not possible.



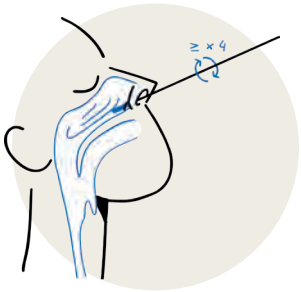
…nasal sampling for less patient discomfort and better protection for healthcare workers.

Nasal sampling can help reduce overall patient discomfort, particularly in sensitive individuals such as children, elderly people and /or people with disabilities.

Besides being less invasive, the test also provides patients with the option to self-collect their nasal sample under the supervision of a healthcare worker. Through reduced physical contact, this method of testing can help decrease the risk of exposure to the virus for healthcare professionals.

Performing a test in 4 easy steps

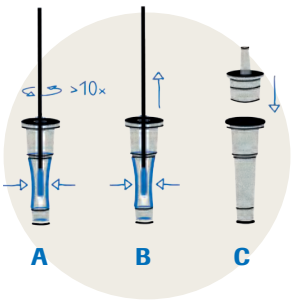
1



Nasal swab collection

Insert a sterile swab 2 cm into the patient's nostril with the most secretion. Rotate the swab 4 times for about 15 seconds against the nasal wall. Remove it from the nostril. Repeat procedure with the same swab in the other nostril.

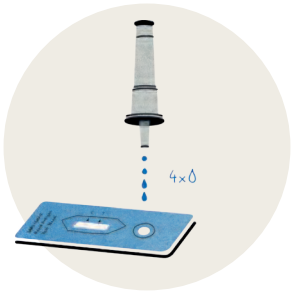
2



Prepare the sample

- **A** Insert the swab into an extraction buffer tube, squeeze the tube and stir the swab >10×.
- **B** Remove the swab while squeezing the sides of the tube.
- **C** Press the nozzle cap tightly onto the tube.

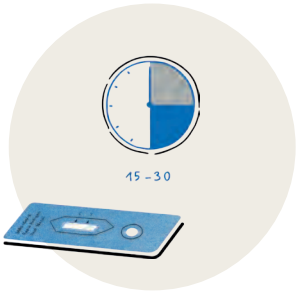
3



Drop of sample

Add 4 drops of extracted sample to the specimen well of the test device.

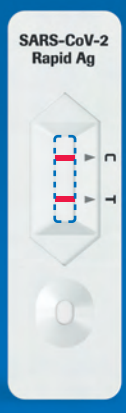
4



Read the test result in 15 – 30 min

Do not read test result after 30 minutes.

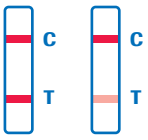
Quick and easy to read



Control line C: Valid, reliable test result

Test line T: SARS-CoV-2 antigen

Positive



Individual has SARS-CoV-2 antigen present indicating active infection.

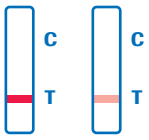
Positive results should not be used as the sole basis for treatment or patient management decisions, and should be considered in the context of the patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Negative

No SARS-CoV-2 antigen detected.

A negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or a molecular assay or ELISA if necessary for patient management.

Invalid



Result not valid
Repeat with a new test.

Do-it-yourself: supervised sample self-collection

The nasal sampling method simplifies the testing procedure, causes less discomfort for patients and offers more protection for healthcare workers.

Nasal swab samples may be self-collected by patients under supervision of a healthcare worker. Sensitive patients can feel more secure and in control of the procedure and frequent testing is made easier and more bearable.

Doctors' offices

Testing sites

Institutions

Performance compared to PCR tests

Direct detection of the virus – through nucleic acid and antigen testing – is essential to contain the virus and make further treatment as well as quarantine decisions.

PCR tests are intended for the qualitative detection of SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples from patients.[2]

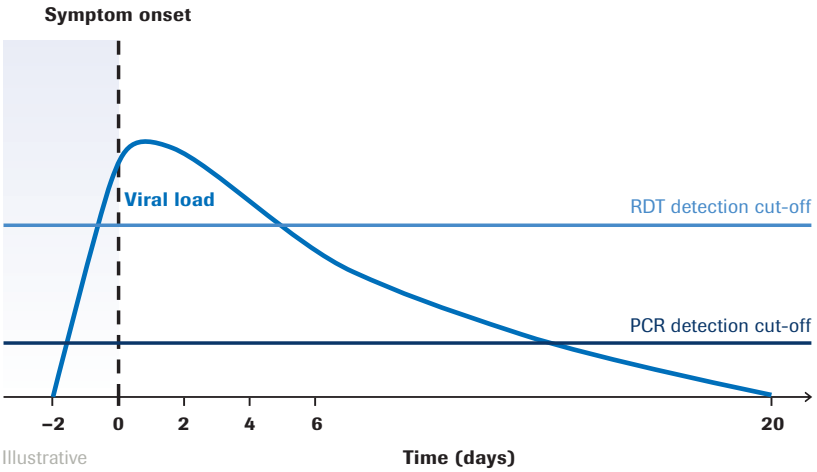
Rapid antigen tests detect the presence of a specific viral protein. A positive result requires a higher viral load than a PCR test for reliable antigen detection and a high test performance.

Centers for Disease Control and Prevention (CDC) recommend rapid antigen testing as diagnostic testing of individuals suspected of COVID-19 or with known or suspected exposure to SARS-CoV-2. (e.g. via contract tracing tools). The World Health Organisation (WHO) recommends screening of asymptomatics environments (institutions, care-homes, schools etc.) where PCR is not immediately available.[3, 4, 5]

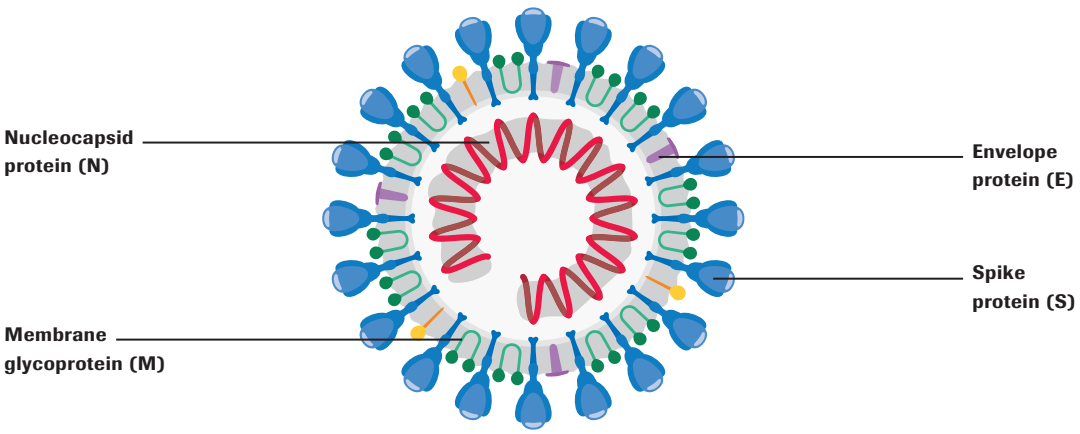
Both institutions recommend antigen testing within 5–7 days post symptom onset as during that time viral load is highest.[3, 4, 5]

PCR tests are considered the gold standard due to the highest analytical sensitivity on the market. However, SARS-CoV-2 rapid antigen tests support to trace infectious individuals in decentralized locations, especially when lab testing isn't available and time is of the essence.

Clinical Sensitivity of a Rapid Test compared to PCR[6]



Structure of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)[7]



Summary of sample characteristics[1]

	Overall	HCP collection	Self-collection
N	**468**	**179**	**289**
Asymptomatic, n/N (%)	**14 / 468** (3.0 %)	**7 / 179** (3.9 %)	**7 / 289** (2.4 %)
Symptomatic, n/N (%)	**454 / 468** (97.0 %)	**172 / 179** (96.1 %)	**282 / 289** (97.6 %)
DPSO, median (range)	**4** (0 – 14)	**4** (1 – 10)	**4** (0 – 14)
PCR positive, n/N (%)	**80 / 468** (17.1 %)	**41 / 179** (22.9 %)	**39 / 289** (13.5 %)
PCR positive symptomatic, n/N (%)	**78 / 80** (97.5 %)	**39 / 41** (95.1 %)	**39 / 39** (100 %)
PCR positive asymptomatic, n/N (%)	**2 / 80** (2.5 %)	**2 / 41** (4.9 %)	**0 / 39** (0 %)
PCR negative, n/N	**388 / 468** (82.9 %)	**138 / 179** (77.1 %)	**250 / 289** (86.5 %)
PCR sample type	Combined OP / NP	Combined OP / NP	Combined OP / NP

Performance overview[1]

For professionally collected samples, the test was found to have a sensitivity of 90.6 % (Ct ≤ 30) and a specificity of 98.6 %.***

Sensitivity	Professional collection	Self-collection
Ct ≤ 24, (95 % CI), N	**100 %** (78.2 % – 100 %), 15	**95.7 %** (78.1 % – 99.9 %), 23
Ct ≤ 27, (95 % CI), N	**92.6 %** (75.7 % – 99.1 %), 27	**92.9 %** (76.5 % – 99.1 %), 28
Ct ≤ 30, (95 % CI), N	**90.6 %** (75.0 % – 98.0 %), 32	**84.4 %** (67.2 % – 94.7 %), 32
Ct ≤ 33, (95 % CI), N	**88.2 %** (72.5 % – 96.7 %), 34	**78.4 %** (61.8 % – 90.2 %), 37
All Ct values, (95 % CI), N	**80.5 %** (65.1 % – 91.2 %), 41	**74.4 %** (57.9 % – 87.0 %), 39
Specificity		
All Ct values, (95 % CI), N	**98.6 %** (94.9 % – 99.8 %), 138	**99.2 %** (97.1 % – 99.9 %), 250

Limit of detection
SARS-CoV-2 (2019-nCOV)
NCCP 43326/2020

Concentration
$3.13 \times 10^{2.2}$ $TCID_{50}$/mL

Dilution Ratio
1/3200

***Vs. comparator RT-PCR: Roche cobas® SARS-CoV-2 and TibMolbiol SARS-CoV-2 E-gene assay.

Your kit for convenient sampling with quick results

→ **Results in 15 – 30 minutes**
→ **Less invasive and more convenient testing**
→ **Increased protection for healthcare workers**

Buffer tube rack

Foil pouch with desiccant (contains one test device)

Instructions for use

Quick reference guide

Sterile swab

Extraction buffer tube

Nozzle cap

Quality controls
One negative and one positive control swab are included in each test kit.

Test device

Ordering information

Product	REF #	GTIN	Cat #	Roche Material #	PZN (DE only)
Languages 1 – 8: Spanish, Portuguese, German, French, Italian, Dutch, Swedish, Turkish					
SARS-CoV-2 Rapid Antigen Test Nasal	9901-NCOV-03G	08809319398233	99COV33D-ML01	09365397023	1173555
Languages 9 – 16: English (CE), Hungarian, Czech, Polish, Russian, Norwegian, Danish, Finnish					
SARS-CoV-2 Rapid Antigen Test Nasal	9901-NCOV-03G	08809319398240	99COV33D-ML02	09365397043	/

References

1 SARS-CoV-2 Rapid Antigen Test Nasal Method Sheet (V1, January 2021).
2 Wölfel, R. et al. (2020). *Virological assessment of hospitalized patients with COVID-2019 581* (7809), 465 – 469.
3 CDC. https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html.
4 Criteria to Guide Evaluation and Laboratory Testing for COVID-19.
Available at: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html. Accessed Sept 11, 2020.
5 COVID-19 (Rapid) Antigen Testing Recommendations WHO update September 11th 2020.
Available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications?publicationtypes=f85a3610-b102-4287-a6df-f3bc0b2e9f7c.
6 Huang, C et al. (2020). *Lancet 395,* 497-506.
7 Masters PS (2006). *Advances in Virus Research. Academic Press. 6*

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