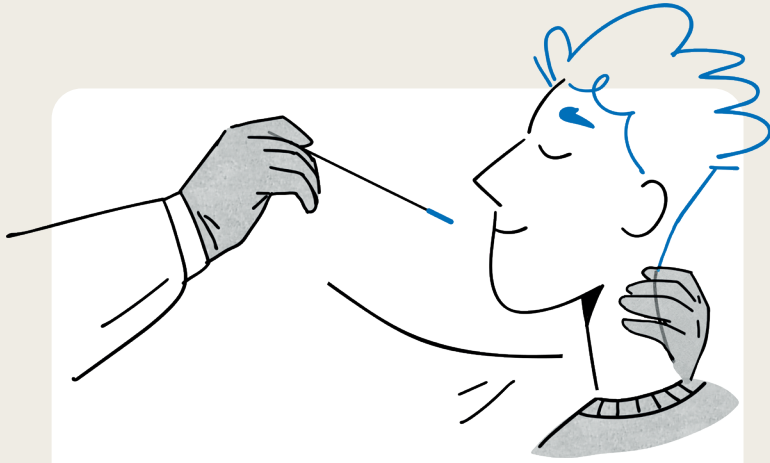


SARS-CoV-2 Rapid Antigen Test Nasal

**Convenient sampling,
quick results**



Introducing the SARS-CoV-2 Rapid Antigen Test Nasal



Nasal swab sample collection

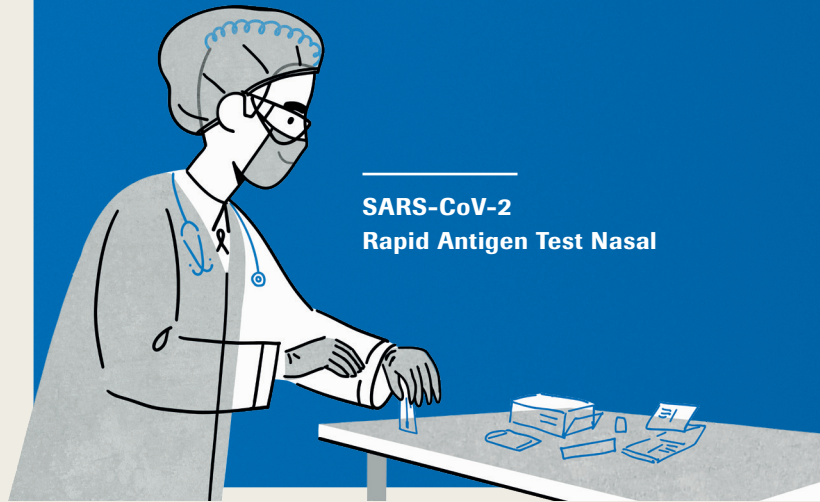
90.6 %
(Ct ≤ 30)

Sensitivity¹

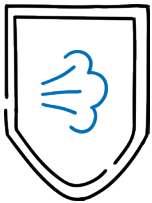
98.6 %

Specificity¹

Convenient sampling,
quick results



SARS-CoV-2
Rapid Antigen Test Nasal



Decreased risk of exposure for healthcare professionals



15 - 30

Results after 15 min



Pre-filled tubes



Target antigen
Nucleocapsid (N)



60

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*



No instruments needed

Key benefit



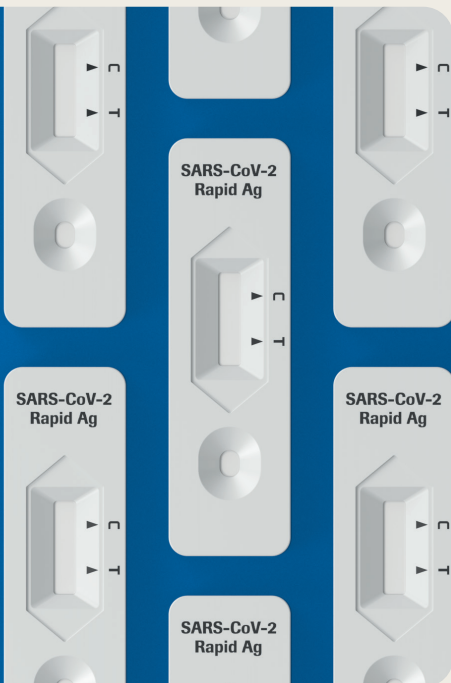
**Shelf life: 24 months
after manufacturing date***



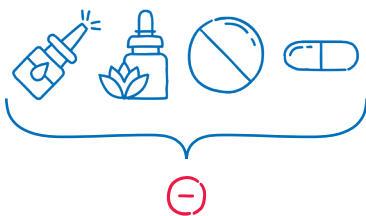
**1 × positive and negative QC
included in the kit**

2–30°C
(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

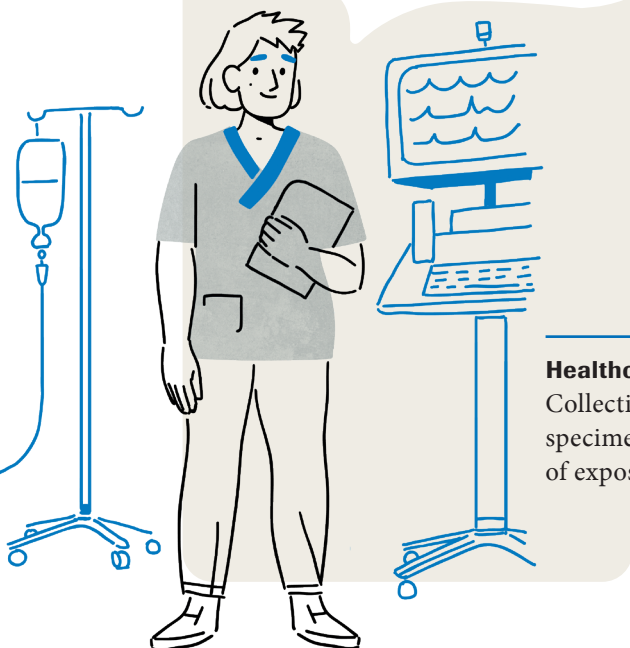
Easier routine testing in point-of-care settings.



Symptomatic patients

Quick results enable fast decision making on self-isolation.

“Is there a less invasive method for testing of more sensitive patients?”



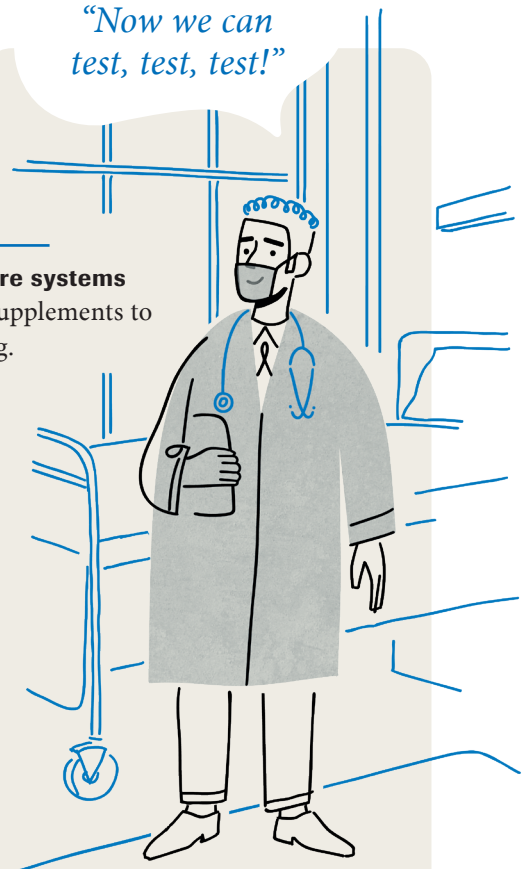
Healthcare professionals

Collection of nasal specimens can decrease risk of exposure.

“Now we can test, test, test!”

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.

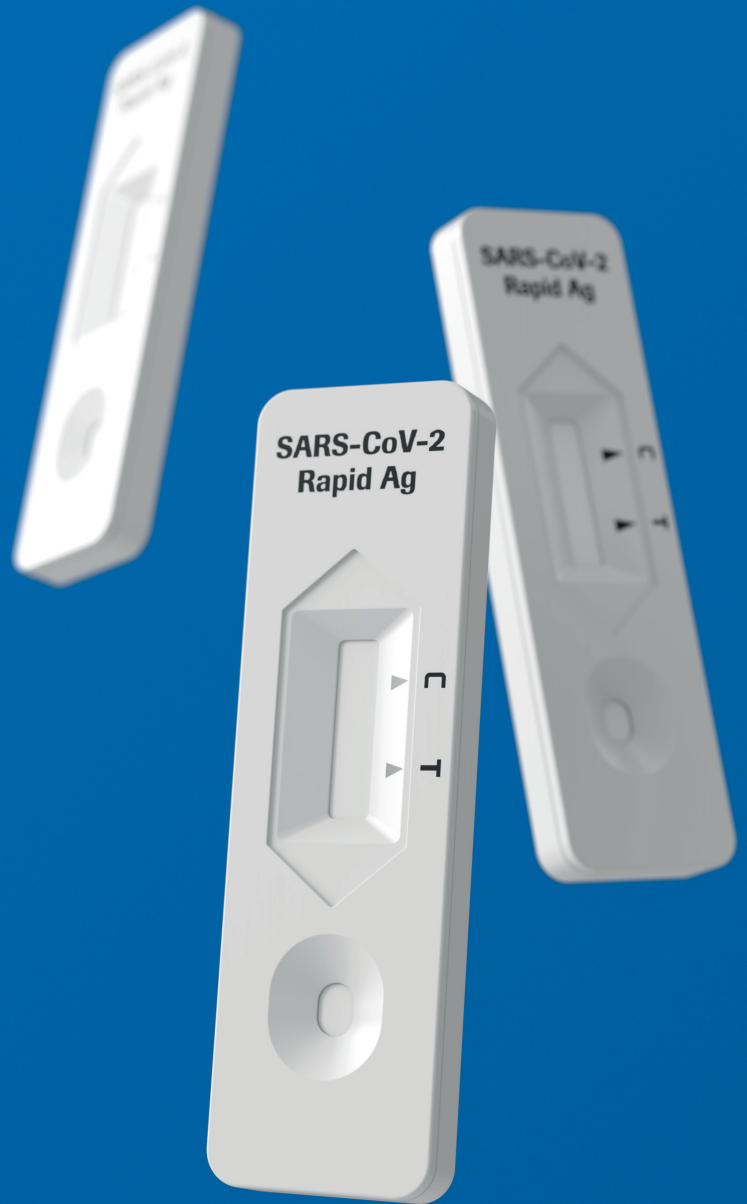
Decision-making on self-isolation for symptomatic patients or asymptomatic individuals with a known or suspected exposure to SARS-CoV-2 can help reduce the risk of passing on the virus. Infected patients who go into quarantine help to protect their contacts such as family, friends and co-workers.

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.*

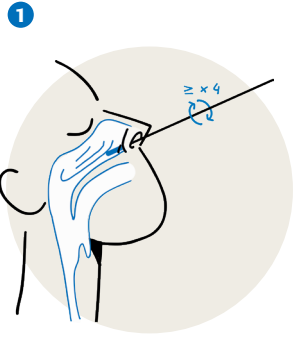
Nasal sampling can help reduce overall patient discomfort, particularly in sensitive individuals such as children, elderly people and/or people with disabilities.

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.



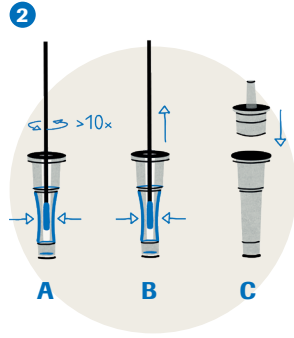
Testing procedure

Performing a test in 4 easy steps



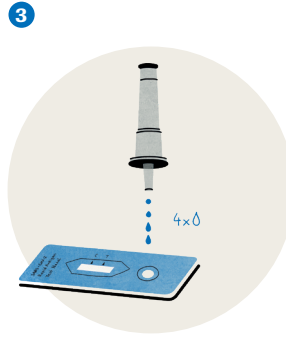
Nasal swab collection

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.



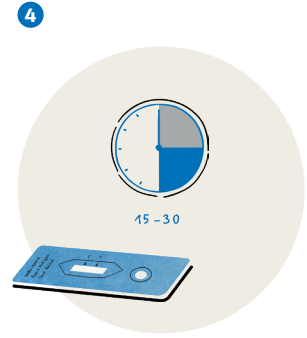
Prepare the sample

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



Drop of sample

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

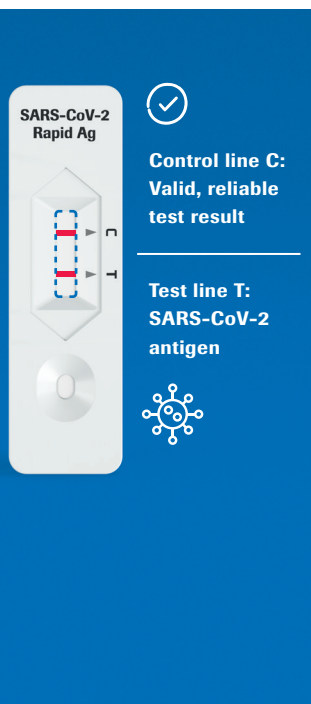


Read the test result in 15 – 30 min

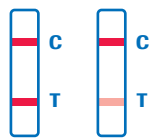


Do not read test result after 30 minutes.

Quick and easy to read



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

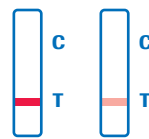


No SARS-CoV-2 antigen detected.

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

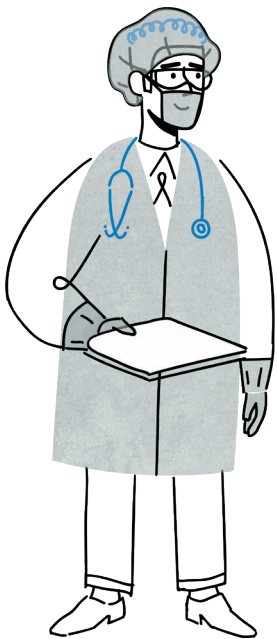


Result not valid Repeat with a new test.

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

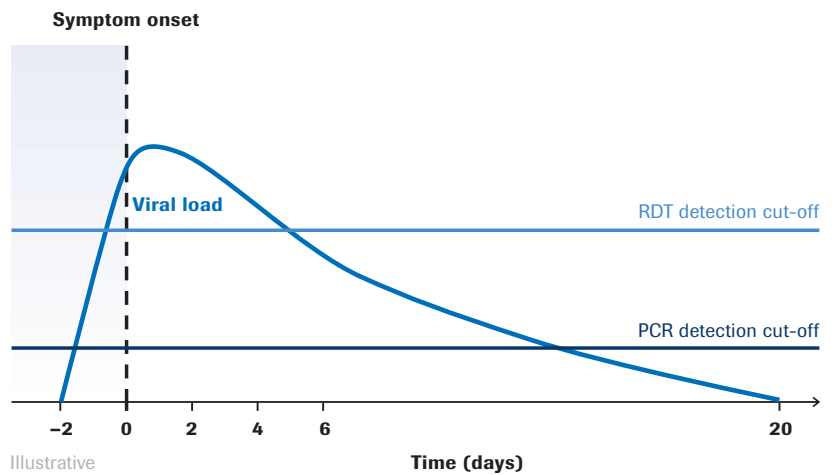
Rapid antigen tests detect the presence of a specific viral protein. A positive result requires a higher viral load than a PCR test for reliable antigen detection and a high test performance.

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 asymptomatic environments (institutions, care-homes, schools etc.) where PCR is not immediately available.^{3,4,5}

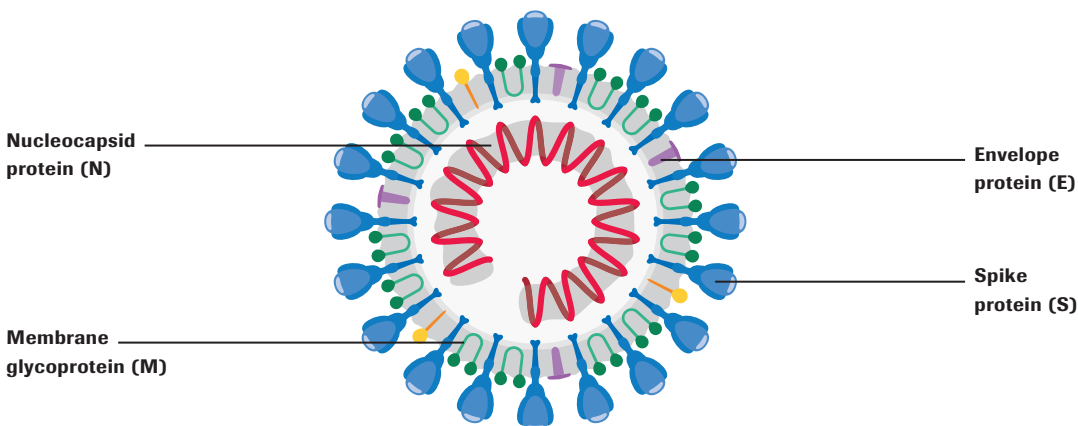
Both institutions recommend antigen testing within 5–7 days post symptom onset as during that time viral load is highest.^{3,4,5}

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 PCR⁶



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



Summary of sample characteristics¹

	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 overview¹

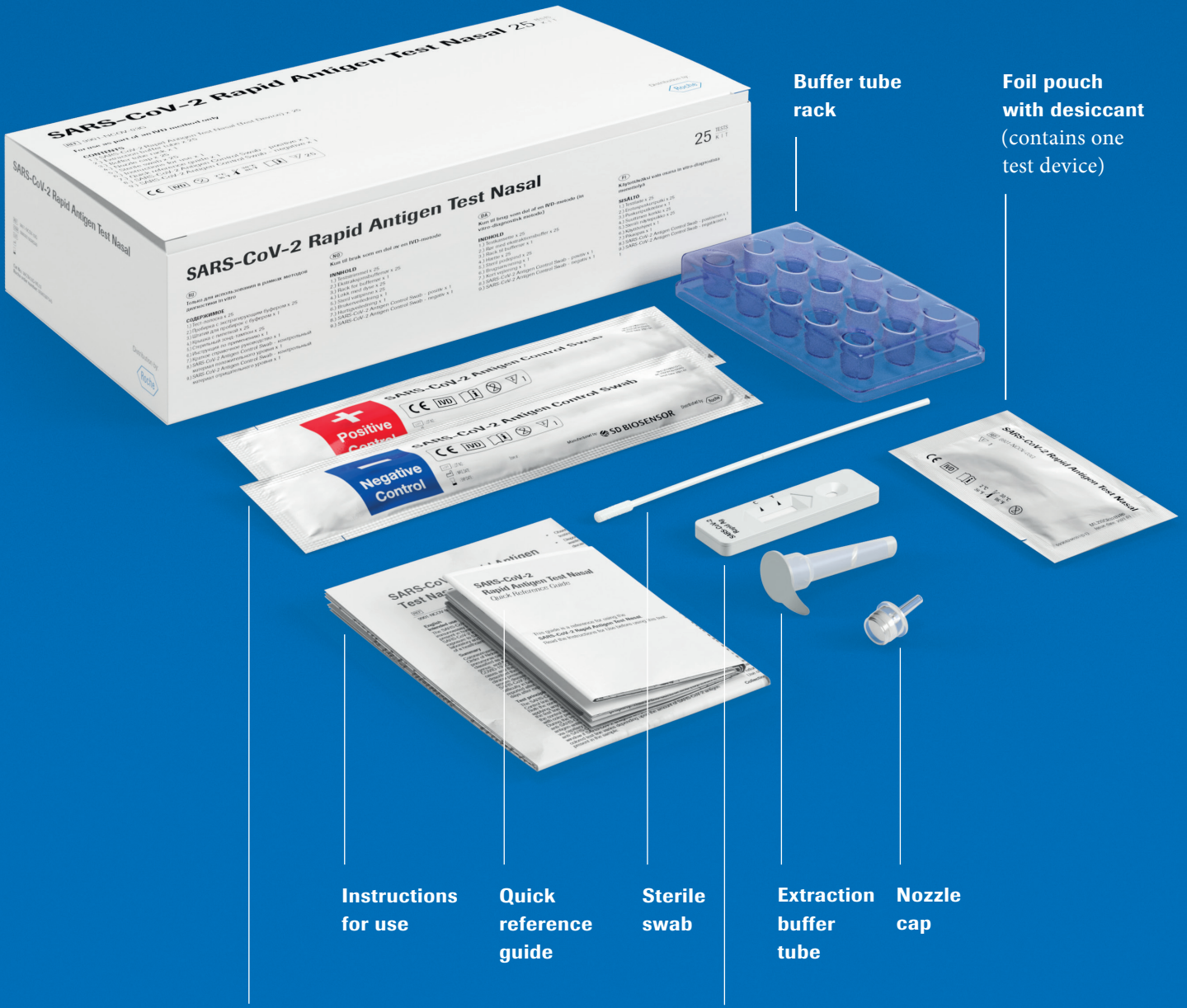
For professionally collected samples, the test was found to have a sensitivity of 90.6 % (Ct ≤ 30) and a specificity of 98.6 %.^{***}

Sensitivity	Professional collection	Self-collection	Limit of detection SARS-CoV-2 (2019-nCoV) NCCP 43326/2020
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	
			Concentration 3.13 × 10 ^{2.2} TCID ₅₀ /mL
			Dilution Ratio 1/3200
Specificity			
All Ct values , (95 % CI), N	98.6 % (94.9 %–99.8 %), 138	99.2 % (97.1 %–99.9 %), 250	

^{***}Vs. comparator RT-PCR: Roche cobas® SARS-CoV-2 and TibMolbiol SARS-CoV-2 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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Medical Approval	Dusanka Kasapic Medical 01-Mar-2021 08:06:12 GMT+0000
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