

SARS-CoV-2 Antigen Self Test Nasal

Testing in your hands

Broadest real-world and manufacturer-independent performance evaluations with > 30,000 samples.^{1,2,3}

Sensitivity: **91.1 %**
(Ct ≤ 30)

Specificity: **99.6 %**



Ordering information

Product	REF #	EAN	Cat #	Roche material #	PZN (DE only)
SARS-CoV-2 Antigen Self Test Nasal	9901-NCOV-06G	08800111704420	99COV130-ML02	09445323077	/

Kit components

Each kit is ready-to-use and contains everything required for performing 5 tests.

- Test device (5x)
(individually in a foil pouch with desiccant)

- Extraction buffer tube (5x)
- Nozzle cap (5x)
- Sterile swab (5x)

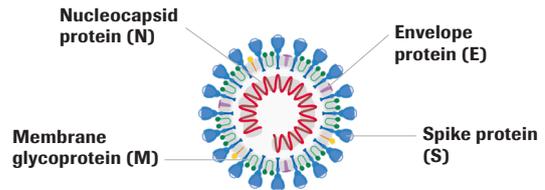
- Instructions for Use and Quick Reference Guide
- Buffer tube holder

Assay characteristics

Test description	The SARS-CoV-2 Antigen Self Test Nasal is a lateral flow test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in human nasal samples. This test is used to detect antigens of the SARS-CoV-2 virus in individuals suspected of having COVID-19. It is designed as a Self Test for patients.
Test type	Qualitative
Sample type	Nasal swab
Target antigen	Nucleocapsid (N)
Time to result	15 minutes (Readout window 15 - 30 minutes)
Storage temperature	2 - 30 °C / 36 - 86 °F
Operating temperature	15 - 30 °C / 59 - 86 °F
Stability (test, opened pouch)	1 hour once the test has been opened

Clinical performance

Clinical performance of the SARS-CoV-2 Antigen Self Test Nasal was evaluated using nasal swab samples from 375 subjects in a prospective study at a clinical center in Germany. The study cohort included adults at high risk for SARS-CoV-2 infection according to clinical suspicion.



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

The following table shows a summary of sample characteristics and results of the clinical evaluation.

	Overall	Self testing	Self collection	Professional collection
N	375	146	96	133
Excluded	2	1 (no AG test performed)	0	1 (no/invalid PCR test)
Asymptomatics	6	0	6	0
Symptomatics	367	145	90	132
DPSO, median	3 (0 - 27)	3 (0 - 10)	3 (0 - 13)	3 (0 - 27)
PCR positive n	110	40	36	34
PCR negative n	263	105	62	96
Age, median (range)	32 (18 - 68)	32 (18 - 68)	31 (18 - 64)	32 (18 - 67)
PCR sample type	Combined nasopharyngeal/oropharyngeal swab (NP/OP) RT-PCR tests Roche cobas® SARS-CoV-2 and TibMolbiol SARS-CoV-2 E-gene assay as the comparator methods;			

The test was found to have a sensitivity of 91.1 % (Ct ≤ 30) and a specificity of 99.6 %.

	Antigen positive / PCR positive	Antigen negative / PCR negative	Relative sensitivity (95 % confidence interval)	Relative specificity (95 % confidence interval)
Self testing**	33/40	105/105	82.5 % (67.2 % - 92.7 %)	100 % (96.5 % - 100 %)
Self collection	31/34	61/62	91.2 % (76.3 % - 98.1 %)	98.4 % (91.3 % - 100 %)
Professional collection*	31/36	96/96	86.1 % (70.5 % - 95.3 %)	100 % (96.2 % - 100 %)
Combined***	95/100	262/263	86.4 % (78.5 % - 92.2 %)	99.6 % (97.9 % - 100 %)
Ct ≤ 30***	92/101	n.a.	91.1 % (83.8 % - 95.8 %)	n.a.
DPSO ≤ 7***	90/103	242/243	87.4 % (79.4 % - 93.1 %)	99.6 % (97.7 % - 100 %)

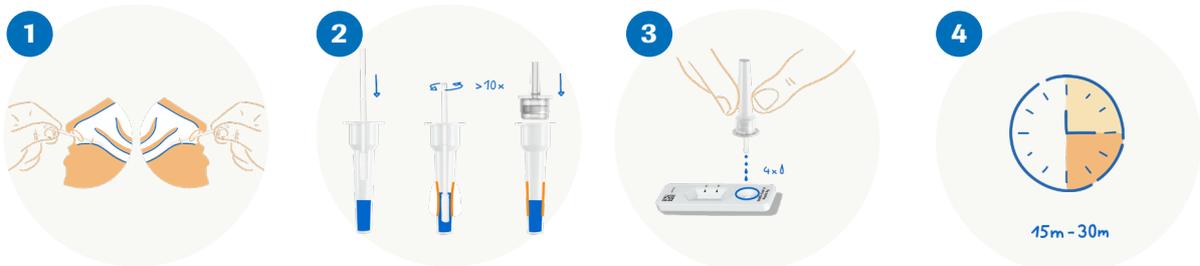
*One sample was excluded from the analysis because the PCR test result was not available.

**One sample (PCR negative) was excluded from the analysis because the antigen test result was not available.

***Ct values are commonly used to estimate the amount of the viral material in samples. A low Ct value suggests the presence of a lot of viral material, and a high Ct value suggests the presence of lower levels of viral material.

Performing a Self Test with a nasal sample

Three simple steps and the result will be ready after 15 minutes



Collect nasal sample

Blow your nose once using a tissue. Insert the swab into one nostril. Slowly slide it approx. 2 cm forward. Rotate the swab 4 times (for approx. 15 seconds) against the lining of the nasal wall, before removing it. Repeat in other nostril using the same swab.

Prepare sample

Insert the swab into an extraction buffer tube, squeeze the tube and stir the swab more than ten times. Remove the swab while squeezing the sides of the tube. Press the nozzle cap tightly onto the tube.

Performing a test

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

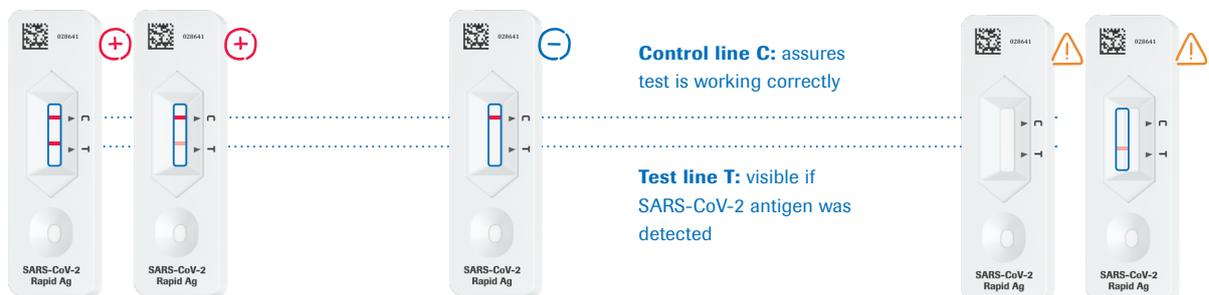


Risk of incorrect results. Do not read test result after 30 minutes.



Wash hands or use hand sanitiser before and after performing a test.

Results interpretation



Positive test result

If both the colored line C and T are visible, the test result is positive. This means the test detected the virus protein in the sample. The tested person is currently infected with SARS-CoV-2.

Negative test result

A visible control line C alone means the test worked correctly. The test result is negative. No virus protein could be detected in the sample.

Invalid test result

If there is no line visible, or only the line marked with a T, the test did not work correctly and needs to be repeated with another test device.

References

1. Dinnes J, et al. *Cochrane Library* (2021); doi.org/10.1002/14651858.CD013705.pub22.
2. Brümmer EL, et al. *medRxiv* (2021); doi.org/10.1101/2021.02.26.212525463.
3. Hayer J, et al. *medRxiv* (2020); doi.org/10.1101/2020.12.22.202486144.
4. Masters PS, *Adv Virus Res* (2006); doi.10.1016/S0065-3527(06)66005-3. Source: SARS-CoV-2 Antigen Self Test Nasal package insert (V1, April 2021)

© 2021 Roche Diagnostics Limited. All rights reserved.

COBAS and NAVIFY are trademarks of Roche. All other product names or trademarks are the property of their respective owners.

Roche Diagnostics Limited

Charles Avenue, Burgess Hill, West Sussex, RH15 9RY.

Company registration number: 571546.

Date of preparation: June 2021.

Document number: MC-UK-00916.

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

diagnostics.roche.com