SARS-CoV-2 Antigen Self Test Nasal

Testing in your hands

Ordering Information

Product	REF #	GTIN	Cat #	Roche Material #	PZN (DE only)
ML01: German, French, Italian, Dutch					
SARS-CoV-2 Antigen Self Test Nasal	9901-NCOV-06G	08800111704413	99COV130J-ML01	09445323023	17386452
ML02: English, French, Swedish, Danish					
SARS-CoV-2 Antigen Self Test Nasal	9901-NCOV-06G	08800111704420	99COV130-ML02	09445323077	/
ML03: Spanish, Portuguese, Greek, Norwegian					
SARS-CoV-2 Antigen Self Test Nasal	9901-NCOV-06G	08800111704437	99COV130J-ML03	09445323070	/

Kit Components

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

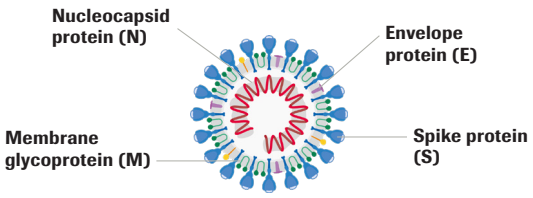
- Test device (5x) (individually in a foil pouch with desiccant)
- Extraction buffer tube (5x)
- Nozzle cap (5x)
- Sterile swab (5x)
- Instructions for Use & Quick Reference Guide
- Buffer tube holder

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)[4]

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;			

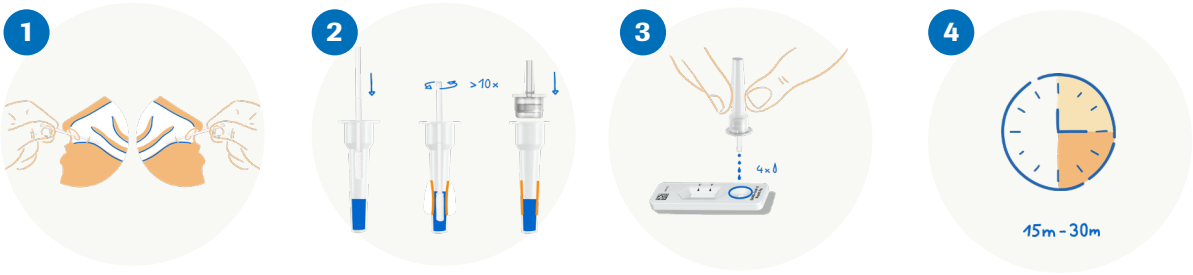
The test was found to have a sensitivity of 91.1 % (Ct ≤ 30) and a specificity of 99.6 %.

	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.

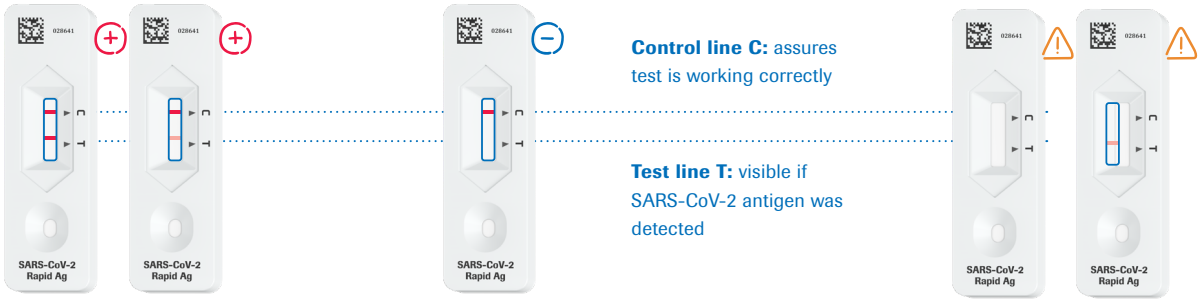
Prepare sample
Insert the swab into an extraction buffer tube, squeeze the tube and stir the swab more than ten times. Remove the swab while squeezing the sides of the tube. Press the nozzle cap tightly onto the tube.

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 sanitizer before and after performing a test.

Results interpretation



Control line C: assures test is working correctly

Test line T: visible if SARS-CoV-2 antigen was detected

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

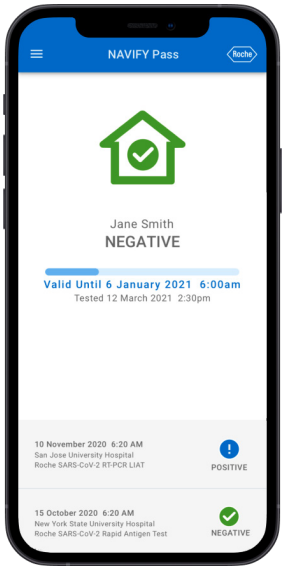
A visible control line C alone means the test worked correctly. The test result is negative. No virus protein could be detected in the sample.

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.

NAVIFY® Pass - a digital solution

NAVIFY Pass can be used to easily share individual COVID-19 related health-data via mobile device.



NAVIFY Pass and self-testing

After performing the Self Test, the user can upload the test result to NAVIFY Pass and easily display their COVID-19 health status to others.

1. Download NAVIFY Pass from app store
2. Register NAVIFY Pass account in the mobile app
3. Perform Self Test
4. Scan data matrix on test device
5. Fill out questionaire and submitting test result
6. Share COVID-19 health-data where needed

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)

Published by

Roche Diagnostics NZ Ltd
ANZ Raranga Building
Level 1, Sylvia Park
286 Mount Wellington Highway
Mount Wellington, Auckland 1060
New Zealand

www.roche.com

TAPS Approval No: 1859