SARS-CoV-2 Rapid Antigen Test Nasal

Convenient sampling, quick results

Sensitivity:
90.6 %
(Ct ≤ 30)

Specificity:
98.6 %

Kit components

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

- Test device (individually in a foil pouch with desiccant)
- Extraction buffer tube and buffer tube rack
- Nozzle cap
- Sterile swab
- Instructions for use and Quick reference guide
- Positive and negative controls

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	/

Assay characteristics

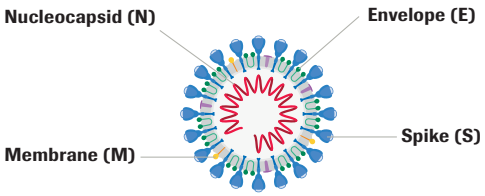
Test description	The SARS-CoV-2 Rapid Antigen Test Nasal is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigen present in human nasal samples. This test is intended to detect antigen from SARS-CoV-2 in individuals suspected of COVID-19 or with known or suspected exposure to SARS-CoV-2. This product is intended for professional use in laboratory and Point of Care environments, or self-collection under the supervision of a healthcare worker.
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
Stability (test, opened pouch)	1 hour once the test has been opened

Clinical performance

Clinical performance of the SARS-CoV-2 Rapid Antigen Test Nasal was evaluated using nasal swab samples from 468 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.

Self-collection was performed under the supervision of healthcare workers without interference or assistance. Test procedures and result reading were always performed by healthcare professionals. High-sensitive RT-PCR tests using combined nasopharyngeal/oropharyngeal swab samples were used as the comparator methods.

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



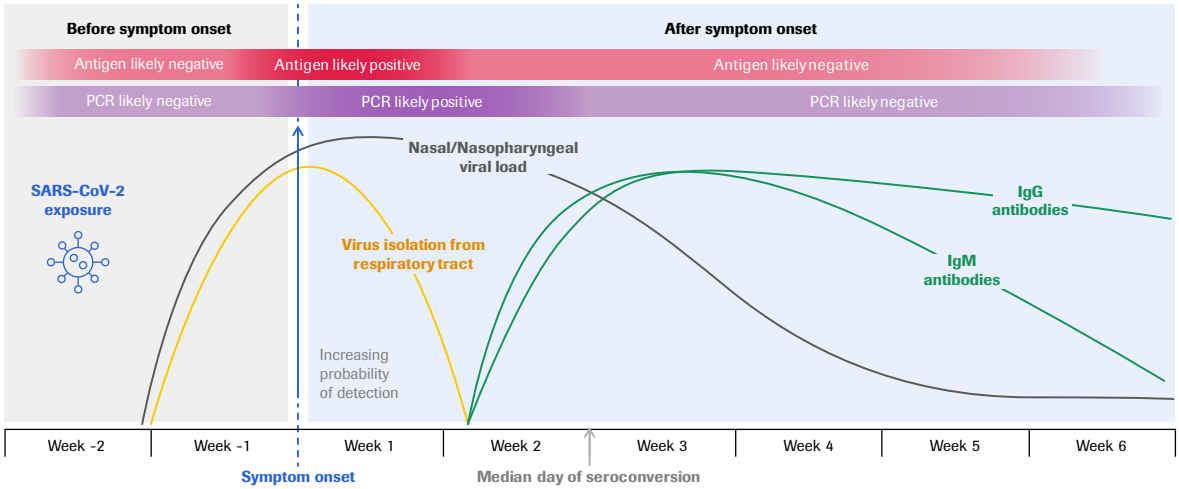
Structure of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)[1]

	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		

The test was found to have a sensitivity of 90.6 % (Ct ≤ 30) and a specificity of 98.6 %.

Relative 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

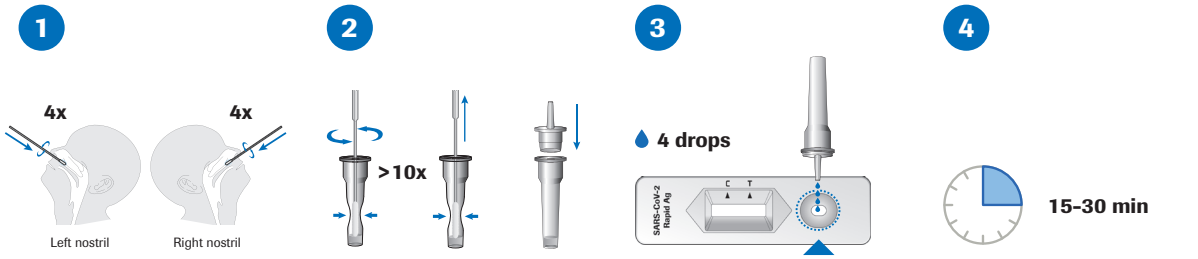
Estimated course of markers in SARS-CoV-2 infection[2-11]



Illustrative only.

Performing a test with a nasal sample

Three simple steps and the result will be ready in 15–30 minutes



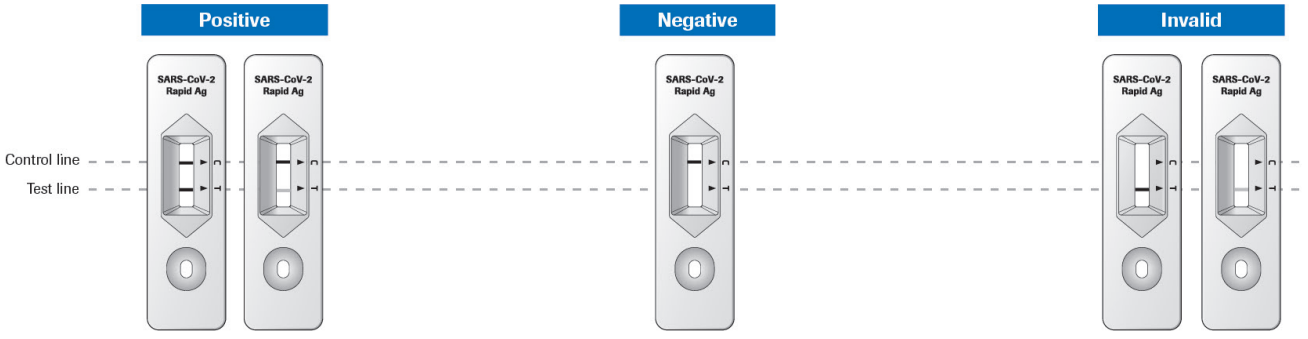
Collect nasal sample
Insert the swab 2 cm (less than 1 inch) into the nostril with the most secretion. Slowly rotate against the nasal wall at least 4 times for a minimum of 15 seconds. Repeat with same swab in other nostril.

Prepare sample
While squeezing the buffer tube, stir the swab more than 10 times. Remove while squeezing the sides of the tube to extract the liquid from the swab. 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.

Results interpretation



Individual has SARS-CoV-2 antigen present, indicating active infection. Confirmation of positive results should be considered using additional laboratory tests, including the patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

No SARS-CoV-2 antigen detected.

Result not valid.
Retest using a new test device.

References

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Company registration number: 571546.
Date of preparation: February 2021.
Document number: MC-IE-00883.

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