SARS-CoV-2 Antigen Self Test Nasal
For Self Testing

REF		SYSTEM	IVD
9901-NCOV-06G	5	visual reading	For in vitro diagnostic use

English

Intended use
SARS-CoV-2 Antigen Self Test Nasal is a lateral flow immunoassay intended for qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in human nasal samples from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.
Persons who test positive with the SARS-CoV-2 Antigen Self Test Nasal should seek follow-up care with their physician or health care provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses.
Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or health care provider.
All test results will be reported to health care providers and relevant public health authorities in accordance with local, provincial and federal requirements.
The SARS-CoV-2 Antigen Self Test Nasal is intended for self-use in individuals aged 16 and older. The test may not be used in children younger than 16 or by lay users to test others.

Summary
At the end of 2019, a novel virus was discovered in a cluster of pneumonia cases.[1] This virus belongs to the large family of Coronaviruses, and has been named SARS-CoV-2 because its genetic sequence is closely related to the virus that caused the SARS outbreak in 2013.[2] The disease caused by SARS-CoV-2 is called COVID-19 (COronaVIrus Disease 2019).[3,4] The course of SARS-CoV-2 infections can vary widely. Some infected individuals do not have any symptoms, others experience relatively mild symptoms such as fever, cough, loss of taste or smell, or diarrhea. But it can also cause more serious symptoms such as difficulty in breathing or even death.[5,6] Usually, it takes 5 - 6 days for symptoms to develop after an exposure to SARS-CoV-2, but sometimes it can take as long as 14 days.[6]

Reagents
- mAb anti-COVID-19 antibody
- mAb anti-chicken-IgY
- mAb anti-COVID-19 antibody-gold conjugate
- purified chicken-IgY-gold conjugate

Precautions and warnings

- Use the test kit once only.
- Remove the test device from the sealed pouch only when you are ready to perform the test.
- Do not use the test kit if the pouch is damaged.
- In the event of a spillage, ensure that it is cleaned thoroughly using a suitable disinfectant.
- Use only the components of this test kit.
- Inadequate or improper sample collection may lead to inaccurate or false results.
- Avoid contact with skin and eyes. In case of accidental contact, rinse well in order to avoid skin irritations. In case of concerns, consult your doctor.
- Keep the test kit away from children to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
- Do not use any of the test components in the body with the exception of the swab included in the kit. Do not swallow any of the components.
- Please consult a medical expert to discuss your test result and to find out whether additional tests are needed. Please also consult a doctor if you have any concerns about your health, if you are experiencing prolonged symptoms, or if your symptoms are worsening.
- Even if your test result is negative, continue to observe all applicable hygiene and safety measures.
- Dispose all waste materials in accordance with local rules.

For customers in the European Economic Area: Contains a SVHC: Octylphenol ethoxylate. Only for use as part of an IVD method and under controlled conditions in accordance with Art. 56.3 and 3.23 of the REACH Regulation.
Prevent release into the environment, drainage system or water bodies.

Storage and stability
Store the kit at 2 - 30 °C / 36 - 86 °F and protect from direct sunlight. The expiry date of the materials is indicated on the external packaging.
Do not freeze the kit.

Materials provided
- Test device (packaged in foil pouch 1 including desiccant package)
- Tube with liquid and nozzle cap (packaged in foil pouch 2)
- Sterile swab[a)]
- Tube holder
- Instructions for Use and Quick Reference Guide

Materials required (but not provided)
- Timer
- Tissue

Test preparation and sample collection
Carefully read the Instructions for Use of the SARS-CoV-2 Antigen Self Test Nasal. Please also see the enclosed Quick Reference Guide (with illustrations) before performing the test.

Preparing for a test
Prior to starting the procedure, the test device and reagents must be equilibrated to operating temperature (15 - 30 °C / 59 - 86 °F).
1. Wash your hands with soap and water or use a hand sanitizer before performing the test.
2. Check the expiry date on the back of the foil pouches. Do not use the test if the expiry date has passed.
3. Open one of the foil pouches 1 by tearing along the tear-line and take out the test device and the desiccant package. Use the test immediatedly after opening the pouch.
4. Ensure that the test device is intact and that there are no green beads in the desiccant package. Do not open the desiccant package.

Collecting and preparing a nasal sample
1. Open the foil pouch 2 by tearing along the tear-line and take out one of the tubes with the liquid and one nozzle cap and place them on the table.
2. Open the seal of the tube carefully without spilling the liquid inside the tube. Place the tube in the tube holder.
3. Blow your nose once using a tissue.
4. Remove the swab from the packaging. Ensure that you only touch the handle of the swab and not the soft pad at the tip.
5. Slightly tilt your head backwards.
6. Insert the swab with the soft pad at the front into your left nostril. Slowly slide the swab approx. 2 cm forward (parallel to the roof of your mouth - not upwards) until you encounter resistance. Do not apply any pressure.
7. Rotate the swab 4 times (for a total of approx. 15 seconds) against the lining of the nasal wall before removing it from the nostril.
8. Repeat steps 6 and 7 in your right nostril using the same swab.
9. Insert the swab into the tube until the soft pad is in the liquid. Squeeze the tube at the bottom and hold it tight. Stir the swab more than 10 times to transfer the biological material from the swab to the liquid.
10. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose the swab and seal the tube securely with the nozzle cap.

The same swab is used to collect samples from both nostrils.

Performing the test
1. Place the test device on a flat surface.
2. Hold the tube upright above the circular well on the test device (not over the rectangular result window).
3. Drop exactly 4 drops onto the circular well. Gently squeeze the sides of the tube together if necessary.
   Note: You can continue with the test even if you accidentally drop 5 drops onto the test device.
4. Set the timer and read the test result after 15 to 30 minutes.
5. Wash your hands with soap and water or use a hand sanitizer after performing the test.

⚠ Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

⚠ Test results that are read before 15 minutes or after 30 minutes may be incorrect.

Interpreting the test results
- **Invalid test result:**
  If a control line (C) is not visible, the result must be considered invalid. The test is not working correctly and you should perform another test using a different test kit. You may have performed the test incorrectly. Carefully read the Instructions for Use and repeat the test. If your test result is still invalid, please contact your doctor or a COVID-19 test center.

- **Positive test result:**
  If a test line (T) is visible together with a control line (C), this means that the result is positive. Look carefully at the result: The test should be considered positive if two lines are visible - even if they are faint. A positive test result means it is very likely that you have COVID-19. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a PCR test to confirm the result.

- **Negative test result:**
  If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is negative. It is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures.
  If you suspect that you have an infection (i.e., if you have prolonged symptoms or if your symptoms are worsening), contact your doctor/primary care physician. You may have another infection, or your test result may be false. You may repeat the test after 1 - 2 days, as COVID-19 cannot be detected with complete accuracy during all stages of an infection.

Limitations of the procedure
- The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
- The test should be used for the detection of SARS-CoV-2 antigen in human nasal swab samples.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- The SARS-CoV-2 Antigen Self Test Nasal may not be used in children younger than 16 or by lay users to test others.
- The SARS-CoV-2 Antigen Self Test Nasal for patient self-testing was evaluated in 3 studies of symptomatic and asymptomatic individuals aged 7 to 78. If the test is to be used on a teenager between 16 to 18 years of age, the test must be performed under adult supervision. For older individuals aged over 61, a helper should also be on hand to provide assistance with testing and result interpretation.
- False negative test results (i.e., an existing infection is falsely not detected) may occur if the antigen level in the specimen is less than the minimum detection limit of the test.
- False negative test results may occur if the specimen was collected incorrectly.
- False negative test results may occur if the specimen swab is not mixed well in the tube (step 9 in the test procedure section).
- Antigen can generally be detected using front nasal swab samples during the acute phase of infection.
- The immune response cannot be evaluated using this test. Other test methods are required for that purpose.
- Positive results indicate the presence of viral antigens. However, a clinical correlation with the case history and other diagnostic information are required to determine the status of the infection.
- Positive results do not exclude the possibility that a bacterial infection or a co-infection with another virus is present.
- Human coronavirus HKU1 could not be tested in the lab. There is a very low probability of cross-reactivity with HKU1.
- False positive results may occur in the presence of SARS-CoV infections.
- Negative results should be viewed as provisional and a PCR test should be performed as confirmation if necessary.
- Negative results do not rule out a SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including decisions about infection control. Individuals who have tested negative and continue to show COVID-19-like symptoms should contact their doctor/primary care physician.
- The performance of the device has not been assessed in a population vaccinated against COVID-19.
- The performance of this test has not yet been clinically validated for use in a pediatric population or for use by a lay user testing another person. Note that performance may differ in these populations. Studies are ongoing.
- The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern.

Specific performance data

Clinical evaluation - Symptomatic subjects
The clinical performance of the SARS-CoV-2 Antigen Self Test Nasal for patient self-testing was evaluated using nasal swab samples collected from 146 (of which, 139 within 7 days post symptom onset) study participants in a prospective study at a clinical center in Germany. The clinical evaluations were performed independently from the manufacturer and distributor within a collaboration between the university hospitals Charité in Berlin and Heidelberg.
The study cohort included symptomatic adults (aged 18 to 68) who were clinically suspected of having a SARS-CoV-2 infection.

The study participants followed written instructions with illustrations for taking a nasal swab sample and performing the test themselves. The samples were collected and the tests performed under the observation of healthcare professionals, who did not intervene at any stage. PCR tests using combined deep nose/deep throat swab samples were used as a comparative method. Nasal sampling by the self-testers always preceded the combined deep nose/deep throat sample collection for RT-PCR comparison. A SARS-CoV-2 infection was diagnosed (using PCR) in 27.4 % of the patients.

Test sensitivity and specificity
In the self-testing study, the SARS-CoV-2 Antigen Self Test Nasal correctly identified 91.2 % (CI: 76.3 % - 98.1 %) of infected study participants with a relatively high viral load (Ct ≤ 30). Individuals with a high viral load are considered to be at higher risk of being infectious and transmitting the virus to others.
For all study participants, the antigen rapid test correctly identified 82.5 % (CI: 67.2 % - 92.7 %) of infected study participants and 100.0 % (CI: 96.5 % - 100.0 %) of non-infected study participants.

	Antigen positive/ PCR positive	Antigen negative/ PCR negative	Relative sensitivity (95% confidence interval)	Relative specificity (95% confidence interval)
Self Testing*	33 out of 40	105 out of 105	82.5 % (67.2 % - 92.7 %)	100 % (96.5 % -100 %)
Ct ≤ 30**	31 out of 34	n.a.	91.2 % (76.3 % - 98.1 %)	n.a.

**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.

Clinical evaluation – Symptomatic and asymptomatic subjects
The clinical performance of the SARS-CoV-2 Antigen Self Test Nasal for patient self-testing was evaluated using nasal swab samples collected from 296 study participants in a multi institution, prospective study in the Republic of Korea. The study cohort included asymptomatic and symptomatic subjects (aged 7 to 91) who were clinically suspected of having a SARS-CoV-2 infection. Symptomatic subjects tested within 5 days of the onset of symptoms.
The study participants followed written instructions with illustrations for taking a nasal swab sample and performing the test themselves. PCR tests using nasopharyngeal swab samples were used as a comparative method. A SARS-CoV-2 infection was diagnosed (using PCR) in 26.7 % of the patients.

Test sensitivity and specificity
The SARS-CoV-2 Antigen Self Test Nasal correctly identified 94.94% (75/79; 95% CI: 87.54% - 98.60%) of infected study participants (symptomatic and asymptomatic). The antigen rapid test correctly identified 100.0 % (217/217; CI: 98.31 % - 100.0 %) of non-infected study participants.

		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen Self Test	Positive	75	0	75
	Negative	4	217	221
Total		79	217	296

The SARS-CoV-2 Antigen Self Test Nasal correctly identified 98.04 % (CI: 89.55 % - 99.95 %) of infected symptomatic study participants and 89.29% (CI: 71.77% - 97.73%) of infected asymptomatic study participants.

	Positive	Negative	Sensitivity
Symptomatic	50	1	98.04% (95% CI: 89.55% - 99.95%)
Asymptomatic	25	3	89.29% (95% CI: 71.77% - 97.73%)
Total	75	4	94.94% (95% CI: 87.54% - 98.60%)

Clinical evaluation – Asymptomatic subjects
The clinical performance of the SARS-CoV-2 Antigen Self Test Nasal for patient self-testing was evaluated using nasal swab samples collected from 326 study participants in a prospective study at a clinical center in Canada. The study cohort included subjects (aged 16 to 78) who were self-declared as asymptomatic.
The study participants followed written instructions with illustrations for taking a nasal swab sample and performing the test themselves. The samples were collected and the tests performed under the observation of healthcare professionals, who did not intervene at any stage. PCR tests using nasopharyngeal swab samples were used as a comparative method. A SARS-CoV-2 infection was diagnosed (using PCR) in 6.44 % of the patients.

Test sensitivity and specificity
The SARS-CoV-2 Antigen Self Test Nasal correctly identified 100% (21/21; 95% CI: 84.5 % - 100 %) of infected study participants. The antigen rapid test correctly identified 98.4 % (300/305; CI: 96.2 % - 99.3 %) of non-infected study participants.

		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen Self Test	Positive	21	1	22
	Negative	0	300	300
	Invalid	0	4	4
Total		21	305	326

Analytical performance

1. Cross-reactivity & microbial interference:
Cross-reactivity was observed for SARS-CoV.

2. Studies of exogenous / endogenous interference substances studies:
No interference was observed with the following substances:
Human blood (Whole Blood, 4 %);
Mucous (Mucin, 0.5 %);
Common nose and throat drops/sprays/candies (Menthol/Benzocaine, 1.5 mg/mL; NeilMed Naso Gel, 5 % v/v; Phenylephrine, 15 % v/v; Oxymetazoline, 15 % v/v; Cromolyn, 15 % v/v; Zicam, 5 % v/v; Alkalol, 1:10 dilution; Phenol Spray, 15 % v/v; Tobramycin, 4 µg/mL);
Other common medicines (Mupirocin, 10 mg/mL; Fluticasone Propionate, 5 % v/v; Oseltamivir Phosphate, 5 mg/mL).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

References

1 Wu et al. Nature. 2020. 579:265–9.
2 Coronaviruses. European Centre for Disease Prevention and Control. https://www.ecdc.europa.eu/en/covid-19/latest-evidence/coronaviruses. Accessed 6 Jan 2021.
3 Coronaviridae Study Group of the International Committee on Taxonomy of Viruses. Nat Microbiol. 2020. 5:536–44.
4 https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-%28covid-2019%29-and-the-virus-that-causes-it.
5 WHO. https://www.who.int/publications-detail-redirect/diagnostic-testing-for-sars-cov-2. Accessed 6 Jan 2021.
6 Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. Accessed 6 Jan 2021.

Symbols
Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

REF	Reference number
LOT	Batch code
IVD	in vitro diagnostic medical device
SYSTEM	Systems on which reagents can be used
GTIN	Global Trade Item Number
UDI	Unique Device Identifier
SN	Serial Number
CE	This product fulfills the requirements of the European Directive 98/79/EC
	Consult instructions for use
	Caution
	Warning
Σ	Contains sufficient for 6 tests
	Use-by date
	Temperature limit
	Do not re-use
	Do not use if package is damaged
	Date of manufacturing
	Manufacturer
	Keep away from sunlight
	Keep product dry
EC REP	Authorized Representative
	Distributor

Additions, deletions or changes are indicated by a change bar in the margin.

a) Swab:

	Swab Manufacturer: Miraclean Technology Co., Ltd. Room 301, Building A, No.18, Rongshuxia Industrial Zone, Tongxin Community, Baolong Street, Longgang District, Shenzhen, 518116 Guangdong, P.R. China	CE 0197 acc. 93/42/EEC
EC REP Swab Authorized Representative Share Info Consultant Service LLC Repräsentanzbüro Heerdter Lohweg 83, 40549 Düsseldorf, Germany		

	SD BIOSENSOR Head office: C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690 REPUBLIC OF KOREA Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161 REPUBLIC OF KOREA www.sdbiosensor.com
Distribution by: Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim www.roche.com Roche order number: 09445323	
EC REP Authorized Representative MT Promedt Consulting GmbH, Altenhofstrasse 80, 66386 St. Ingbert Germany	

For all questions about the SARS-CoV-2 Antigen Self Test Nasal that are not answered in this package insert, there is a FAQ document available on the Roche Canada website (www.rochecanada.com). Please look for the documentation section via the search engine on the website. Please contact Roche Care Center for technical questions at 1-877-273-3433.
The SARS-CoV-2 Antigen Self Test is distributed in Canada by:
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Laval, Quebec (Canada) H7V 4A2

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