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
The SARS-CoV-2 Antigen Self Test Nasal is a so-called 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.

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.
- If you suspect the presence of blood on the swab, discard the swab and repeat the test with a fresh one.
- 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. 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.
11. 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 for patient self-testing was evaluated in a study of symptomatic adults aged 18 to 68. If the test is to be used on a child or teenager under 18 years of age, the test must be performed by an adult or 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.

Specific performance data

Clinical evaluation
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.

In the patient self-testing group, 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.

The clinical performance of the SARS-CoV-2 Antigen Self Test Nasal was also evaluated for professional testing following patient self-collection and professional collection of nasal swab samples in the same clinical center. 229 adults who were clinically suspected of having a SARS-CoV-2 infection were included in the prospective study. 133 study participants (thereof 126 within 7 days post symptom onset) underwent nasal sampling performed by healthcare professionals and 96 study participants (thereof 83 within 7 days post symptom onset) followed instructions for collecting their nasal swab samples themselves. Self-collection was performed under the supervision of healthcare professionals. PCR tests were performed as described above.

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.

In all 3 cohorts together, 110 PCR-positive and 263 PCR-negative study participants were evaluated using the SARS-CoV-2 Antigen Self Test Nasal. For patients with a relatively high viral load (Ct ≤ 30), the relative sensitivity was 91.1 % (95 % CI: 83.8 % - 95.8 %, N=101). For all samples, the overall relative sensitivity and the overall relative specificity were 86.4 % (95 % CI: 78.5 % - 92.2 %) and 99.6 % (95 % CI: 97.9 % - 100.0 %), respectively.

For patients tested within 7 days post symptom onset (DPSO), the relative sensitivity was 87.4 % (95 % CI: 79.4 % - 93.1 %) and the relative specificity was 99.6 % (95 % CI: 97.7 % - 100.0 %).

	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 %)
Self collection	31 out of 34	61 out of 62	91.2 % (76.3 % - 98.1 %)	98.4 % (91.3 % - 100 %)
Professional collection*	31 out of 36	96 out of 96	86.1 % (70.5 % - 95.3 %)	100 % (96.2 % - 100 %)
Combined*,**	95 out of 110	262 out of 263	86.4 % (78.5 % - 92.2 %)	**99.6 % (97.9 % - 100 %)**
Ct ≤ 30***	92 out of 101	n.a.	**91.1 % (83.8 % - 95.8 %)**	n.a.
DPSO ≤ 7*,**	90 out of 103	242 out of 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.

Analytical performance
1. Cross-reactivity & microbial interference:
There was no cross-reactivity and interference with the following microbes: Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus, Adenovirus Type 1, Adenovirus Type 2, Adenovirus Type 5, Adenovirus Type 6, Adenovirus Type 7 A, Adenovirus Type 11, Adenovirus Type 14, Adenovirus Type 40, Human Metapneumovirus 3 Type B1, Human Metapneumovirus 16 Type A 1, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4A, Influenza A H1N1 pdm/Michigan/45/15, Influenza A H1N1 Brisbane/59/07, Influenza A H3N2 Singapore/INFIMH-16-0019/16, Influenza A H3N2 South Australia/55/14, Influenza A H3N2 Hong Kong/8/68, Influenza A H3N2 Victoria/361/11, Influenza B Massachusetts/2/12, Influenza B Malaysia/2506/04, Influenza B Lee/40, Influenza B Yamagata/16/88, Influenza B Victoria/2/87, Influenza B Texas/6/11, Influenza B Colorado/6/17, Influenza B Florida/02/06, Enterovirus type 68 09/2014 Isolate 4, Respiratory syncytial virus A, Respiratory syncytial virus B, Rhinovirus 1A, Rhinovirus A16, Rhinovirus B42, Haemophilus influenzae (NCCP 13815), Haemophilus influenzae (NCCP 13819), Haemophilus influenzae (NCCP 14581), Haemophilus influenzae (NCCP 14582), Streptococcus pneumoniae Type 1 (KCCM 41560), Streptococcus pneumoniae Type 2 (KCCM 40410), Streptococcus pneumoniae Type 3 (KCCM 41569), Streptococcus pneumoniae Type 5 (KCCM 41570), Streptococcus pyogenes (ATCC 12344), Candida albicans (ATCC 10231), Bordetella pertussis (NCCP 13671), Mycoplasma pneumoniae (ATCC 15531), Chlamydia pneumoniae (ATCC VR-2282), Legionella pneumophila (ATCC 33155), Staphylococcus aureus (NCCP 14647), Staphylococcus epidermidis (KCCM 35494).
Cross-reactivity was observed for SARS-CoV.
Note: Human coronavirus HKU1 has not been tested. There can be cross-reaction with human coronavirus HKU1 even though the percentage identity of the nucleocapsid protein sequence of HKU1 with the nucleocapsid protein sequence of SARS-CoV-2 was 31.6 %, which is considered as low homology.

2. Studies of exogenous / endogenous interference substances studies:
There was no interference with the following substances at indicated concentrations:
Chloraseptic (Menthol/Benzocaine) (1.5 mg/mL), Naso GEL (NeilMed) (5 % v/v), CVS Health Nasal Drops (Phenylephrine) (15 % v/v), Afrin (Oxymetazoline) (15 % v/v), CVS Health Oxymetazoline (15 % v/v), CVS Health Nasal Spray (Cromolyn) (15 % v/v), Zicam (5 % v/v), Homeopathic (Alkalol) (1:10 dilution), Sore Throat Phenol Spray (15 % v/v), Tobramycin (4 µg/mL), Mupirocin (10 mg/mL), CVS Health Fluticasone Propionate (5 % v/v), Tamiflu (Oseltamivir Phosphate) (5 mg/mL), Whole Blood (4 %), Mucin (0.5 %).

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 <n> 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	European 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
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EC REP	Authorized Representative MT Promedt Consulting GmbH, Altenhofstrasse 80, 66386 St. Ingbert Germany

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