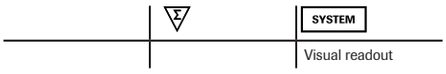
SARS-CoV-2 Rapid Antigen Test
Nasal with Self-Test Waiver

User Instructions for Consumers



English

Intended use

The SARS-CoV-2 Rapid Antigen Test Nasal is a fast, lateral flow test for the qualitative detection of the SARS-CoV-2 nucleocapsid antigen in human nasal swabs. This test is used to detect the SARS-CoV-2 virus antigens in humans suspected of being infected with COVID-19. The test is intended for self-sampling and self-testing completed by the person to be tested.

Summary

Coronaviruses are enveloped, positive-strand RNA viruses from the Nidovirales family.[1] A new coronavirus was discovered at the end of 2019 in connection with an increase in the number of pneumonia cases.[2] This new coronavirus, now known as SARS-CoV-2, was classified as belonging to the Sarbecovirus subgenus within the Betacoronavirus genus. The disease caused by a SARS-CoV-2 infection was called COVID-19 (Corona Virus Disease 2019).[3,4] Due to the rapidly increasing number of cases and the extent of the worldwide spread, the SARS-CoV-2 situation was declared a pandemic by the World Health Organisation (WHO) on 11th March 2020.[5] The clinical presentation of SARS-CoV-2 can vary from asymptomatic infections to severe illness and even death.[6,7] Symptoms in patients with a confirmed SARS-CoV-2 infection range from fever and a dry cough, to shortness of breath and respiratory distress. In addition, patients have been reported to have diarrhoea and a loss of taste and/or smell after a SARS-CoV-2 infection.[6,7]
Symptoms can occur up to 14 days after exposure.[7,6]

Reagents

- MAb - anti-COVID-19 antibody
- MAb - anti-chicken IgY
- MAb - anti-COVID-19 antibody gold conjugate
- Purified chicken IgY gold conjugate

Precautions and measures

The packaging contains components classified in accordance with Regulation (EC) No.1272/2008:

Warning:

H317	May cause allergic skin reactions.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long-lasting effects.

Prevention:

P261	Avoid breathing in dust/fumes/gas/mist/vapour/ aerosol.
P273	Avoid release of P273 into the environment.
P280	Wear protective gloves/goggles/face protection.

Reaction:

P333 + P313	In case of skin irritation or a rash: consult a doctor.
P337 + P313	In case of persistent eye irritation: consult a doctor.
P362 + P364	Take off and wash contaminated clothing before reuse.

For customers in the European Economic Area: contains a very high-risk substance (SVHC): Octyl-/nonylphenol ethoxylate. Only to be used as part of an IVD method and under controlled conditions - according to articles 56.3 and 3.23 of the REACH regulation.
Do not allow to enter the environment, sewage system or water.

- Only use the test kit once.
- Do not use the test kit if the packaging pouch is damaged.
- Thoroughly clean with a suitable disinfectant in case of spillage.
- Do not use any of the test components on the body, with the exception of the enclosed cotton swab.
- Carefully read through and follow the government's "Information for self-test users" instructions before using the test. You will still need to continue to adhere to all applicable protection and hygiene measures, even if the test result is negative.

The product safety label is in accordance with the GHS regulations applicable in the EU. Contact: telephone number +49-621-7590 for all countries.

In vitro diagnostic tool

You will need to observe the usual precautions when handling laboratory reagents. All waste should be disposed of in accordance with local guidelines. A safety information sheet for professional users is available upon request.

Storage and shelf life

Store the packaging at 2-30°C/36-86°F and not in direct sunlight. The materials are stable until the indicated expiration date stated on the outer packaging. Do not store the packaging in a freezer.

Materials supplied

- Test strip (packed separately in a packaging pouch with a desiccant bag)
- Tube with test liquid
- Dropper cap
- The positive and negative controls are not applicable to self-testing
- User instructions/abbreviated manual for consumers Government instructions

Not supplied

- Holder for test liquid tube

Additional materials required

- Stopwatch/timer

Test preparation and sample collection

Carefully read the SARS-CoV-2 Rapid Antigen Test Nasal user instructions. Please also refer to the attached quick guide (with images) before completing the test.

Preparing the test

The test strips and reagents must be brought to the correct operating temperature (15-30°C/59-86°F) before the procedure can be started.

1. Check the expiry date on the back of the packaging pouch. Do not use the test strip if the expiry date has passed.
2. Open the packaging pouch along the tear line and remove the test strip and desiccant bag. Use the test immediately after opening the pouch.
3. Check whether the test strip is intact and whether the desiccant status indicator is yellow (=suitable for use).

Taking a sample (nasal swab)

1. Blow your nose
2. Wash your hands with soap and water, or use a disinfecting hand gel before completing the test. Open the test liquid tube by pulling the tab and removing the foil. Hold the tube in your hand, or position it in a holder. (Not supplied.)
3. Remove the cotton swab from the packaging by pulling the two tabs on the plastic foil. Make sure you only touch the cotton swab by the handle, not the tip with the "cotton ball".
4. Tilt your head back slightly.
5. First insert the cotton swab into one nostril with the "cotton ball" at the front. Slowly push the cotton swab forward about 2 cm (parallel to the palate - towards the pharynx, not up) until you start feeling some resistance. Do not exert any pressure.
6. Roll the cotton swab firmly around the inside of the nostril 4 times (approximately 15 seconds) and remove it from the nostril.
7. Repeat steps 4 and 5 with the same cotton swab in the other nostril. The same cotton swab is used to obtain a sample from both nostrils.

Completing the test

1. Place the cotton swab in the tube with test liquid. Squeeze the bottom of the tube and twist the cotton swab back and forth more than 10 times.
2. Continue pinching the sides of the tube while you remove the cotton swab, making sure all of the test liquid is squeezed out of the cotton swab.
3. Firmly press the dropper cap onto the tube.
4. Place the test strip on a flat surface. Hold the tube in a vertical position above the circular area (not the rectangular results window). Allow exactly 4 drops to fall onto the test area. Carefully squeeze the tube if necessary.
   Comment: You can continue with the test if you accidentally deposit 5 drops onto the test area.
5. Set the stopwatch and read the test result after 15-30 minutes.

Not pinching the tube whilst removing the cotton swab can result in an incorrect result because of an excess of test liquid on the cotton swab.

Don't read the test result after more than 30 minutes have passed, as the result may then no longer be correct.

Interpreting the test results

- Invalid test result:
  The result should be considered as invalid (the test didn't work properly) if no control line (C) is visible. Take a good look at the result: the test can be regarded as valid even if only a faint control line is visible. You may not have completed the test correctly. Carefully read through the user instructions and repeat the test. You will need to contact your doctor or a COVID-19 test centre if you continue to see an invalid test result.
- Positive test result:
  The presence of a test line (T), no matter how faint, together with a control line (C) means a positive test result.
  A positive result means you probably have COVID-19. Carefully follow the government's "Information for self-test users" instructions. Your doctor may prescribe a PCR test to confirm your result.
- The presence of a control line (C) (no matter how faint), but no test line (T) means a negative result. This means it's unlikely you have COVID-19.
  Even with a negative test result, you will still need to continue to observe all the protective and hygienic measures in place. Carefully follow the government's "Information for self-test users" instructions.
  There is still a chance that you have been infected if you see a negative test result. Repeating the test after 1-2 days is recommended in case of uncertain cases (for example, in case of persistent symptoms, or your symptoms have become more serious), as the coronavirus can't be accurately detected during all stages of an infection.

Limitations of the procedure

- The test procedure, precautions and interpretation of the test results must be strictly followed whilst completing the procedure.
- The test is intended for the detection of the SARS-CoV-2 antigen in samples of human nasal swabs.
- Quantitative values of the SARS-CoV-2 antigen concentration can't be determined, as this is a qualitative test.
- The SARS-CoV-2 Rapid Antigen Test Nasal for self-testing by consumers was evaluated in a study of symptomatic adults aged 18-68. Adolescents/children under 18 years of age must either be supervised by an adult when completing the test, or alternatively they must have the test completed by an adult. People over the age of 61 should seek the support of a care provider when completing and evaluating the test.
- The antigen is generally detectable during the acute phase of the infection in nasal swabs from the front section of the nose.
- An assessment of the immune response (antibodies) is not possible with this test. Other test methods are required for this.
- Positive results indicate the presence of viral antigens, but a clinical correlation with someone's medical history and other diagnostic information is required to determine the infection status.
- Positive results do not rule out a bacterial infection or a possible co-infection with other viruses.
- Negative results should be regarded as preliminary results and, if necessary, a confirmatory PCR test should subsequently be completed too.
- Even with a negative test result, you will still need to continue to observe all the protective and hygienic measures in place.
- Carefully follow the government's "Information for self-test users" instructions.

Clinical evaluation

The clinical presentation of the SARS-CoV-2 Rapid Antigen Test Nasal for self-testing by patients was assessed using nasal swabs from 146 trial subjects in a prospective study conducted in a clinical centre in Berlin. 138 of these samples were included within 7 days of the onset of symptoms. The study cohort consisted of symptomatic adults (aged 18 to 68), clinically suspected of having contracted the SARS-CoV-2 infection. Study participants followed written and illustrated instructions to take a nasal swab and complete the test themselves. The collecting of samples and completing the test was observed by medical professionals without intervention. PCR tests with combined nasopharyngeal/ oropharyngeal swabs were used as comparison methods. The nasal sample collection always preceded the combined NP/OP sample collection. A SARS-CoV-2 infection was diagnosed in 27.4% of the patients (using the PCR test).
The SARS-CoV-2 Rapid Antigen Test Nasal clinical performance has also been assessed for professional self-collection or professional collection of nasal swabs at the same clinical centre. 468 adults who were clinically suspected of having contracted a SARS-CoV-2 infection were prospectively included. 179 study participants (155 of these within 7 days of the onset of symptoms) underwent nasal sampling by medically trained personnel. 289 study participants (244 of these within 7 days of the onset of symptoms) followed written instructions for the self-collection of a nasal swab. The patients' self-collecting was completed under the supervision of professional care providers without intervention. PCR tests with combined nasopharyngeal/oropharyngeal swabs were used as comparison methods.
The nasal sample collection always preceded the combined NP/OP sample collection.

Test sensitivity and specificity

In the self-test study, the Rapid Antigen Test Nasal correctly identified 82.5% (CI: 67.2% - 92.7%) of those infected and 100.0% (CI: 96.5% - 100.0%) of those not infected. If the test had been completed within the first 5 days of the onset of symptoms, the test correctly identified 86.2% (CI: 68.3% - 96.1%) of the infected people identified by a PCR test. This means that, out of the 100 actually infected patients, the test detected 83 infected patients. If the test is completed within the first 5 days of the onset of symptoms, the test will correctly identify 86 of 100 infected patients. For patient samples taken within 7 days of the onset of symptoms, we can summarise the results in the following pooled performance rating of the test of the three study cohorts described above. The test showed a sensitivity of 83.3% and a specificity of 99.1%. A summary of all patient samples taken within 7 days of the onset of symptoms:

	PCR positive	PCR negative	Total
Antigen positive	85	4	89
Antigen negative	17	431	448
Total	102	435	537
Sensitivity	**83.3% (95%CI: 74.7% - 90.0%)**		
Specificity	**99.1% (95%CI: 97.7% - 99.7%)**		

Analytical performance

1. Detection limit (LoD)
The SARS-CoV-2 positive sample was acquired by adding a SARS-CoV-2 negative nasal swab, confirmed with a PCR test, to inactivated SARS-CoV-2 (2019-nCOV), strain NCCP 43326/2020/Korea. The LoD was determined by testing a dilution series of artificial positive samples like 9.25 x 101.2 TCID50/ml for direct nasal swabs.

2. Cross-reactivity and microbial interference
No cross-reactivity or interference was found with the following micro-organisms at the stated concentrations:

Human coronavirus 229E (1 x 105.5 TCID50/ml), human coronavirus OC43 (1 x 107.77 TCID50/ml), human coronavirus NL63 (1 x 105.07 TCID50/ml), MERS-Coronavirus (4.17 x 105 TCID50/ml), Adenovirus-type 1 (2.57 x 108 TCID50/ml), Adenovirus type 2 (1.15 x 107 TCID50/ml), Adenovirus type 5 (1 x 107.53 TCID50/ml), Adenovirus type 6 (1 x 107.29 TCID50/ml), Adenovirus type 7A (1 x 105.15 TCID50/ml), Adenovirus type 11 (1 x 107.29 TCID50/ml), Adenovirus type 14 (1 x 105.39 TCID50/ml), Adenovirus type 40 (1 x 106.58 TCID50/ml), human Metapneumovirus 3 type B1 (1 x 106.34 TCID50/ml), human Metapneumovirus 16 Type A1 (1 x 106.98 TCID50/ml), Parainfluenza virus 1 (1 x 108.49 TCID50/ml), Parainfluenza virus 2 (1 x 106.10 TCID50/ml), Parainfluenza virus 3 (1 x 106.82 TCID50/ml), Parainfluenza virus 4A (1 x 106.58 TCID50/ml), Influenza A H1N1 pdm/Michigan/45/15 (1 x 106.10 TCID50/ml), Influenza A H1N1 Brisbane/59/07 (1 x 105.86 TCID50/ml), Influenza A H3N2 Singapore/INFIMH-16-0019/16 (4.68 x 104 TCID50/m L), Influenza A H3N2 South Australia/55/14 (1 x 105.07 TCID50/ml), Influenza A H3N2 Hong Kong/8/68 (1 x 105.70 TCID50/ml), Influenza A H3N2 Victoria/361/11 (1 x 105.15 TCID50/ml), Influenza B Massachusetts/2/12 (1 x 105.39 TCID50/ml), Influenza B Malaysia/2506/04 (1 x 105.07 TCID50/ml), Influenza B Lee/40 (1 x 105.39 TCID50/ml)), Influenza B Yamagata/16/88 (1 x 105.39 TCID50/ml), Influenza B Victoria/2/87 (1.86 x 104 TCID50/ml), Influenza B Texas/6/11 (1 x 106.58 TCID50/ml), Influenza B Colorado/6/17 (4.68 x 104 TCID50/ml), Influenza B Florida/02/06 (3.8 x 106 TCID50/ml), Enterovirus Type 68 09/2014 Isolate 4 (3.55 x 105 TCID50/ml), Respiratory syncytial virus A (1 x 106.58 TCID50/ml), Respiratory syncytial virus B (5.01 x 105 TCID50/ml), Rhinovirus 1A (1 x 105.55 TCID50/ml), Rhinovirus A16 (1 x 106.1 TCID50/ml), Rhinovirus B42 (1.41 x 105 TCID50/ml), *Haemophilus influenzae* (NCCP 13815) (2.54 x 107 KbE/ml), *Haemophilus influenzae* (NCCP 13819) (3.39 x 107 KbE/ml), *Haemophilus influenzae* (NCCP 14581) (4.10 x 107 KbE/ml), *Haemophilus influenzae* (NCCP 14582) (1.06 x 107 KbE/ml), *Streptococcus pneumoniae* Type 1 (KCCM 41560) (1.54 x 106 KbE/ml), *Streptococcus pneumoniae* Type 2 (KCCM 40410) (1.04 x 107 KbE/ml), *Streptococcus pneumoniae* Type 3 (KCCM 41569) (1.34 x 107 KbE/ml), *Streptococcus pneumoniae* Type 5 (KCCM 41570) (1.24 x 107 KbE/ml), *Streptococcus pyogenes* (ATCC 12344) (3.22 x 107 KbE/ml), *Candida albicans* (ATCC 10231) (1.78 x 106 KbE/ml), *Bordetella pertussis* (NCCP 13671) (6.24 x 107 KbE/ml), *Mycoplasma pneumoniae* (ATCC 15531) (2.48 x 109 KbE/ml), *Chlamydia pneumoniae* (ATCC VR-2282) (9.1 x 107 IFU/ml), *Legionella pneumophila* (ATCC 33155) (1.9 x 108 KbE/ml), *Staphylococcus aureus* (NCCP 14647) (1.00 x 109 KbE/ml), *Staphylococcus epidermidis* (KCCM 35494) (6.22 x 108 KbE/ml).

Cross-reactivity for SARS-CoV was observed.

Comment: Human coronavirus HKU1, *Pneumocystis jirovecii* (PJP) and *Mycobacterium tuberculosis* were not tested. A cross-reaction with the human coronavirus HKU1, PJP or TB is possible, although the percentage similarity of the nucleocapsid protein sequence of HKU1 and the proteins of PJP and TB with the nucleocapsid protein sequence of SARS-CoV-2 amounts to 31.6%, 12.3 % and 13.0%, which is considered to be minimal.

3. Research into exogenous/endogenous interfering substances
At the stated concentrations, no interference was found with the following substances:
Chloraseptic (menthol/benzocaine) (1.5 mg/ml), Naso GEL (NeilMed) (5% v/v), CVS Health nose drops (phenylephrine) (15% v/v), Afrin (oxymetazoline) (15% v/v) v), CVS Health Oxymetazoline (15% v/v), CVS Health Nose Spray (Cromolyne) (15% v/v), Zicam (5% v/v), homeopathic agent (Alkalol) (1:10 dilution), phenol spray for sore throat (15% v/v), tobramycin (4 pg/ml), mupirocin (10 mg/ml), CVS Health fluticasone propionate (5% v/v), Tamiflu (oseltamivir phosphate) (5 mg/ml), whole blood (4%), mucin (0.5%).

4. High-Dose-Hook-Effect:
SARS-CoV-2 virus culture was added to samples. The SARS-CoV-2 virus culture showed no Hook-effect up to 1 x 106.2 TCID50/ml.
In order to indicate the boundary between the whole number and the fractional part of a number, this method sheet always uses a full stop as the decimal separator. No thousands separators are used.

Literature

1 Coronaviruses. European Centre for Disease Prevention and Control. https://www.ecdc.europa.eu/en/covid-19/latest-evidence/coronaviruses. Accessed 6 Jan 2021
2 Wu et al. Natuur. 2020. 579:265-9.
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/technicalgui- dance/ naming-the-coronavirus-disease-%28covid-2019%29-and-the-virus-that-causes-it
5 WHO. https://www.who.int/dg/speeches/detail/who-director-general-s-opening-re- marks-at-the-media-briefing-on-covid-19 --- 11-March-2020. Accessed 6 Jan 2021.
6 WHO. https://www.who.int/publications-detail-redirect/diagnostic-testing-for-sars-two-. Accessed 6 Jan 2021.
7 Centres for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. Accessed 6 Jan 2021.

Symbols

REF	Reference number
LOT	Batch number
IVD	In vitro diagnostic tool
	Please note
	Follow the user instructions
	Contents sufficient for <n> tests
	Best before
	Temperature limits
SYSTEM	Systems on which the reagents can be used
GTIN	Global article number GTIN
	Only use once
UDI	Unique product identification number
	Do not use if the packaging is damaged
	Production date
	Manufacturer
	Do not expose to direct sunlight
	Store the product in a dry place

This test, to be used as a self-test, has been made available under a temporary waiver with reference 1848272-220041-GMT, as published on http://www.rijksoverheid.nl/ontheffingen-antigeentesten.

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EC REP **Temporary Representative**
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SARS-CoV-2 Rapid Antigen Test Nasal with Self-Test Waiver

Brief summary for consumers

These instructions will assist you with using the **SARS-CoV-2 Rapid Antigen Test Nasal**.
You must read the consumer user instructions before using the test.

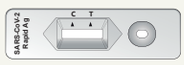
Important safety information

⚠ Warning!

- Wash your hands with soap and water, or use a disinfecting hand gel before completing the test.
- Keep the cotton swab clean. Don't touch the tip of the cotton swab and make sure it doesn't touch any surfaces before you use it.

Test kit components

Test strips



Packing pouches and desiccant bags

Tube with test liquid and dropper cap

Sterile cotton swab

You must keep these components close to hand when completing the test:

- Test strips (packed separately in a packaging pouch with a desiccant bag)
- Tube with test liquid
- Dropper cap
- Sterile cotton swab

What else you will need:

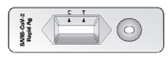
- Stopwatch

1 Preparing the test

1. Carefully read through the consumer user instructions for the **SARS-CoV-2 Rapid Antigen Test Nasal**, scan the QR code for the instructional video.

2. Check the expiry date on the back of the packaging pouch. Do not use the test if the expiry date has passed.

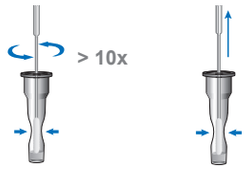
3. Open the packaging pouch along the tear line and remove the test strip and desiccant bag.
4. Check whether the test strip is intact and whether the desiccant status indicator is yellow (= suitable for use).



2 Taking and preparing a nasal swab

1. Blow your nose before completing the test.
2. Wash your hands with soap and water, or use a disinfecting hand gel.
3. Open the test liquid tube by pulling the tab and removing the foil. Hold the tube in your hand, or position it in a holder. (Not supplied).
4. Remove the cotton swab from the packaging. Make sure you only touch the cotton swab by the handle, not the tip with the "cotton ball".
5. Tilt your head back slightly.
6. First insert the cotton swab into one nostril with the "cotton ball" at the front. Slowly push the cotton swab forward about 2 cm (parallel to the palate - towards the pharynx, not up) until you start feeling some resistance. Do not exert any pressure.
7. Roll the cotton swab firmly around the inside of the nostril 4 times (approximately 15 seconds) and remove it from the nostril.
8. Repeat steps 6 and 7 with the same cotton swab in the other nostril.
   Comment: Samples from both nostrils must be taken with the same cotton swab.

9. Place the cotton swab in the tube with test liquid. Squeeze the bottom of the tube and twist the cotton swab back and forth more than 10 times.
10. Continue pinching the sides of the tube while you remove the cotton swab, making sure all of the test liquid is squeezed out of the cotton swab.

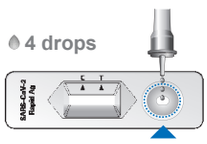


WARNING! Not pinching the tube can result in an incorrect result because of an excess of test liquid on the cotton swab.

11. Carefully close the tube with the dropper cap. Continue with **3 Complete the test.**

3 Complete the test

1. Place the test strip on a flat surface.
2. Hold the tube in a vertical position above the circular area (not the rectangular results window).
3. Allow exactly 4 drops to fall onto the test area. Carefully squeeze the tube if necessary.
   Comment: You can continue with the test if you accidentally deposit 5 drops onto the test area.



4. Set the stopwatch and read the test result after 15 to 30 minutes.

   WARNING! Don't read the test result **after more than 30 minutes** have passed, as the result may then no longer be correct.

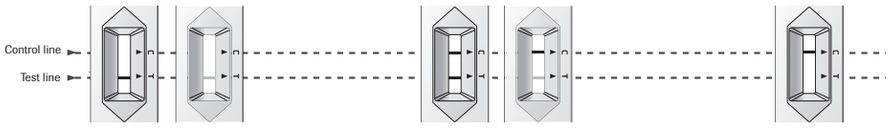
Scan the QR code for the instructional Video

4 Interpreting the results

Invalid test result

Positive test result

Negative test result



1. The result should be considered as invalid if no control line (C) is visible.
   The test didn't work properly and you will need to complete a new test with a new test kit.
   You may not have completed the test correctly. Carefully read through the user instructions and repeat the test.
   Carefully follow the government's "Information for self-test users" instructions.

   Take a good look at the result: the test can be regarded as valid even if only a faint control (C) line is visible.

2. The presence of a test line (T) together with a control line (C) means a positive test result.
   Take a good look at the result: the test can be regarded as positive even if only a faint test line is visible.
   A positive test result means you probably have COVID-19.
   Carefully follow the government's "Information for self-test users" instructions. Your doctor may prescribe a PCR test to confirm your result.

3. The presence of a control line (C) (no matter how faint), but no test line (T) means a negative result.
   This means it's unlikely you have COVID-19.
   Even with a negative test result, you will still need to continue to observe all the protective and hygienic measures in place.
   Carefully follow the government's "Information for self-test users" instructions.

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Revision date: April 2021

This test has been introduced to the market under a temporary waiver with reference 1848272-220041-GMT, as published on http://www.rijksoverheid.nl/ontheffingen-antigeentesten.