Novacheck ®

SARS-CoV-2 Antigen Rapid Test Self-Test

INSTRUCTIONS FOR USE

IVD

Intended use

The Novacheck® SARS-CoV-2 Rapid Test is a sandwich immunochromatographic assay containing two specific antibodies for the qualitative detection of nucleocapsid protein antigen in human nasal swab specimens. This test kit is for the detection of SARS-CoV-2 N-protein antigen occurring in the acute phase of infection.
An antigen is usually detectable in upper respiratory tract samples during the acute phase of infection (within the first 5 to 7 days after the onset of symptoms).
The Novacheck® SARS-CoV-2 rapid test can only be used for lay people in symptomatic individuals. This test is intended for use as a home self-test only. The user should not make any decision of medical relevance without first consulting their physician.

Diagnostic value

COVID-19 is an acute respiratory infectious disease caused by the novel coronavirus SARS-CoV-2. The main routes of transmission of the infection are symptomatic and asymptomatic persons who have become infected. The incubation period of the virus is up to 14 days, but usually only 5 to 6 days. The main symptoms of the disease are loss of smell and taste, fever, weakness, fatigue and dry cough. In some cases, stuffy noses, shortness of breath, sore throat and myalgia are also observed.
Positive test results confirm the presence of SARS-CoV-2 antigens, but a clinical history is also needed to determine the status of the infection. Positive results do not exclude the possibility of bacterial infection or coinfection with other viruses.
Despite the negative test results, COVID-19 should not be completely ignored. The results should be evaluated together with recent exposure to the virus, medical history and the presence of clinical signs and symptoms.

Working principle of the test

The Novacheck® SARS-CoV-2 rapid test is based on sandwich immunochromatographic polymer technology for the qualitative detection of nucleocapsid protein antigen in human nasal swab specimens. The sample is mixed with the coloured polymer-labelled monoclonal SARS-CoV-2 antibody 1 in the sample well of the test cassette and chromatographed together with the nitrocellulose membrane. In the example, if SARS-CoV-2 antigens are present, they bind to SARS-CoV-2 antibody 1. The mixture then binds to the immobile SARS-CoV-2 antibody 2 on the nitrocellulose membrane. The resulting complex of antibody 1, antigen and antibody 2 forms the coloured test line. The control line of the test cassette is covered with secondary antibodies and gives a coloured result when the test is performed normally.

Component

SARS-CoV-2 antigen test cassette, dropper tube filled with extraction buffer, test swab (sterile)

Materials required that are not included in the test kit: Clock or timer

Storage and shelf life

Store between 2 °C and 30 °C, do not freeze, protect from light. Shelf life: 24 months.
Expiry date: See label.

Sample material

To avoid false or invalid results caused, for example, by contamination of the sample or improper storage, the procedure should be carried out immediately after sampling.

The used test kit must be disposed of according to local regulations.

Test procedure
Please wash your hands with soap or disinfect your hands before and after performing the test.

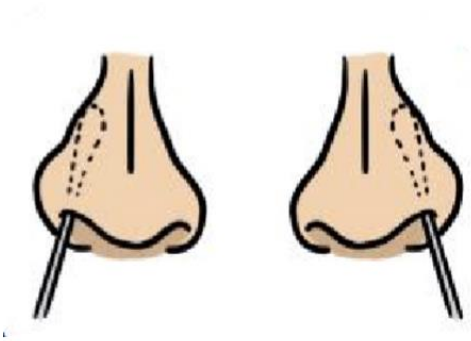
1. Please read the instructions carefully before using the test.

2. Bring all components and samples to room temperature. Then open the foil pouch, remove the test cassette and place it on a flat and clean work surface away from direct sunlight. The test should be used within one hour of removal from the foil pouch.

3. Nasal swabs are taken as shown below:

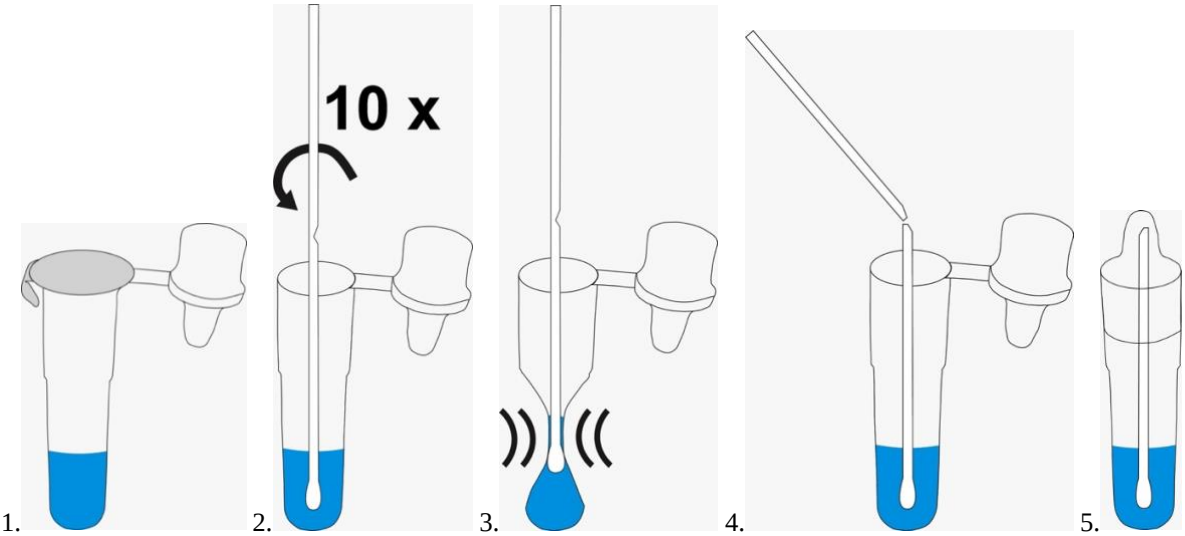
   Caution. Do not touch or contaminate the sampling area of the swab.

   Insert the **test stick about 2.5 cm into the nostril**. Rotate the test stick five times on the inner surface of your nostril to collect mucus and cells. Repeat this process in the other nostril.

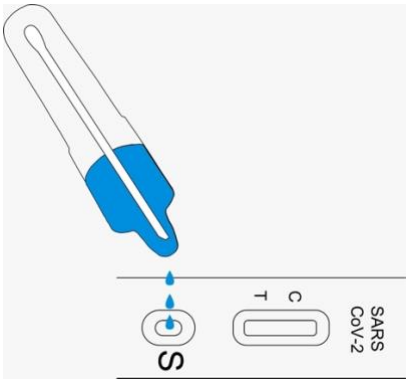


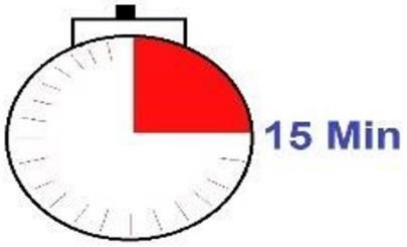
Preparation of the sample solution:

1. Remove the aluminium seal from the sample tube
2. Place the test stick in the test tube and turn it at least 10 times.
3. Press the tip of the swab along the inner wall of the sample tube to keep the liquid in the tube as much as possible.
4. Break off the test stick at the marked point and leave the lower part in the test tube.
5. Press the dropper cap into the bottle opening. Stir well by turning the tube or shaking it slightly downwards.



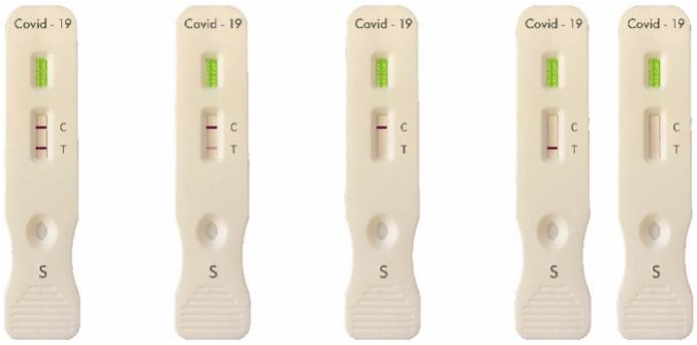
Application of the sample:
Drop 3 drops of the sample solution into the designated well (S) of the test cassette and wait for the result.





Read the result 15 minutes after applying the sample. Do not read the result after 20 minutes.

Evaluation of the test results
Positive: A red line appears in the area of the control (C) as well as the test line (T). Even if the red line is only faintly visible at (T), the test must be evaluated as positive **or weakly positive.** This indicates the presence of SARS-CoV-2 antigens at a concentration above the detection limit.
Negative: The red line is only visible in the control (C) area, not in the test line (T) area. This means that the sample does not contain SARS-CoV-2 antigen or that the antigen concentration is below the detection limit of the test.
Invalid: The test is invalid if the red line in the control area (C) is not visible.



positive weak positive negative invalid

Clinical performance*
The results of the Novacheck® SARS-CoV-2 rapid test and the PCR test are shown in the table below:

Summary of the performance of the SARS-CoV-2 antigen rapid test compared to RT-PCR

Subject kits	Clinical diagnosis		Total
	（+）Positive	（-）Negative	
（+）Positive	328	0	328
（-）Negative	14	517	531
Total	342	517	859

Sensitivity = 95.91%；95% CI: 93.25%～97.55%.
Specificity = 99.9%; 95% CI: 99.26%～100.00%.

*Clinical performance was studied in parallel with diagnostic PCR and antigen testing in 342 individuals who were positive for covid-19 within seven (7) days of symptom onset.

Detection limit: 1.7×10^{2} TCID50/ml
The detection limit was determined from positive samples diluted with the sample matrix of nasal swabs.

Hook effect
The test results of this product showed no hook effect for the SARS-CoV-2 antigen at a concentration of 3.4×10^{5} TCID50/mL (CT value≤25).
Cross-reactivity: The cross-reactivity of the test was tested with various microorganisms and viruses. No cross-reactivity was found with certain concentrations of the following viruses and microorganisms:

Name	Concentration	Test results
Influenza B/Y amagata	1.00×10TCID50/ml ^{2}	Negative
Influenza B/Voctoria	1.07×10^{5} TCID50/ml	Negative
Influenza A H1N1	1.00×10^{2} TCID50/ml	Negative
Influenza A H3N2	1.15×10^{2} TCID50/ml	Negative
Adenovirus 3	1.24×10^{5} TCID50/ml	Negative
Adenovirus 7	1.87×10^{6} TCID50/ml	Negative
Human coronavirus 229E	1.00×10^{5} TCID50/ml	Negative
Human coronavirus OC43	2.00×10^{6} TCID50/ml	Negative
Human coronavirus NL63	2.00×10^{6} TCID50/ml	Negative
MERS coronavirus	2.00×10^{6} TCID50/ml	Negative
Cytomegalovirus	1.00×10^{5} TCID50/ml	Negative
Enterovirus 71	2.55×10^{5} TCID50/ml	Negative
Human parainfluenza virus 1	1.35×10^{5} TCID50/ml	Negative
Human parainfluenza virus 2	6.31×10^{5} TCID50/ml	Negative
Human parainfluenza virus 3	3.25×10^{5} TCID50/ml	Negative
Measles virus	6.31×10^{5} TCID50/ml	Negative
Mumps virus	6.31×10^{6} TCID50/ml	Negative
Respiratory syncytial virus	2.00×10^{5} TCID50/ml	Negative
Rhinovirus 1A	1.26×10^{5} TCID50/ml	Negative
Bacillus pertussis	1.30×10^{6} CFU/ml	Negative
Chlamydophila pneumoniae	1.00×10CFU/mL ^{5}	Negative
Escherichia coli	1.00×10CFU/mL ^{5}	Negative
Haemophilus influenzae	1.20×10CFU/mL ^{6}	Negative
Mycobacterium binding	1.00×10CFU/mL ^{5}	Negative
Mycoplasma pneumoniae	1.00×10CFU/mL ^{6}	Negative
Neisseria meningococcus	1.00×10CFU/mL ^{5}	Negative
Neisseria gonorrhoeae	1.00×10CFU/mL ^{5}	Negative
Pseudomonas aeruginosa	3.70×10CFU/mL ^{6}	Negative
Staphylococcus aureus	2.20×10CFU/mL ^{6}	Negative
Streptococcus pneumoniae	1.00×10CFU/mL ^{6}	Negative
Streptococcus pyogenes	1.28×10CFU/mL ^{6}	Negative

Streptococcus salivarius	1.00×10CFU/mL [5]	Negative

Interfering substances: The table below shows the results of interference testing of SARS-CoV-2 negative and SARS-Cov-2 positive samples with endogenous and exogenous potentially interfering substances.

Name of the interacting substance	**Concentration**	**Negative interaction result**	**Positive interaction result**
Muzin	5%	Negative	Positive
Thoroughbred	5% (V/V)	Negative	Positive
α-Interferon	500 thousand IU/mL	Negative	Positive
Zanamivir	500 ng/ml	Negative	Positive
Ribavirin	20 μg/ml	Negative	Positive
Oseltamivir	5 μg/ml	Negative	Positive
Peramivir	0.2 mg/ml	Negative	Positive
Lopinavir	8 mg/ml	Negative	Positive
Ritonavir	530 μg/ml	Negative	Positive
Umifenovir	4μg/mL	Negative	Positive
Levofloxacin	30μg/ml	Negative	Positive
Azithromycin	4.5μg/ml	Negative	Positive
Ceftriaxone	0.8mg/ml	Negative	Positive
Meropenem	1.1mg/ml	Negative	Positive
Tobramycin	4ng/ml	Negative	Positive
Phenylephrine	20μg/ml	Negative	Positive
Oxymetazoline	0.1mg/ml	Negative	Positive
Beclomethasone	0.1mg/ml	Negative	Positive
Dexamethasone	2 mg/ml	Negative	Positive
Flunisolid	0.1mg/ml	Negative	Positive
Triamcinolone acetonide	10.5ng/ml	Negative	Positive
Budesonide	2.75ng/ml	Negative	Positive
Mometasone	10ng/ml	Negative	Positive
Fluticasone	55μg/ml	Negative	Positive
Histamine hydrochloride	10ng/ml	Negative	Positive
Sodium chloride	5%	Negative	Positive

Limits of the review process

1. The contents of this kit are for the qualitative detection of SARS CoV-2 antigens from nasal swabs.
2. A negative test result may occur if the antigen content in a sample is below the detection limit of the test or if the sample was not properly collected/stored.
3. Errors in the administration of the test may affect the test performance and/or invalidate the test result.
4. Test results should be interpreted in the context of other clinical data presented to the physician.
5. Positive test results do not exclude the possibility of co-infection with other pathogens.
6. Negative test results do not rule out other viral or bacterial infections.
7. Negative results should be considered possible and confirmed by clinical molecular testing, including infection control, if necessary.
8. Clinical performance is assessed with frozen samples and performance may vary with fresh samples.
9. Sample stability recommendations are based on influenza test stability data and performance may vary depending on SARS-CoV-2. The specimen should be tested immediately after collection, as soon as possible.
10. If differentiation of specific SARS viruses and strains is required, additional tests should be performed.
11. This IVD (in vitro diagnostic device) has been evaluated for use with human specimens only.
12. The clinical evaluation study was conducted only with symptomatic individuals with suspected SARS-CoV-2 infection. Consequently, the performance of the test may be reduced in asymptomatic individuals due to the lower amount of viral material in the sample. Therefore, in asymptomatic individuals, the test should be performed at least twice within three days, with a minimum of twenty-four hours and a maximum of 48 hours between tests. You may need to buy additional tests to perform these serial (repeat) tests. The background is that the probability of detecting SARS-CoV-2 infection in asymptomatic persons with this test increases until the day of the disease outbreak.
13. Compared to the RT-PCR SARS-CoV-2 test, the sensitivity of this test was observed to decrease after the first five days after the onset of symptoms.
14. The validity of the Novacheck® SARS-CoV-2 rapid test is not specified for the identification/verification of tissue culture isolates and should not be used for this function.

Security guidelines

1. Only suitable for use for in vitro diagnosis in humans.
2. Please read all operating instructions before testing.
3. Do not use reagents whose expiry date has passed.
4. In case of contact of the sample extraction solution with skin or eyes, rinse with plenty of water.
5. All components are for single use only.
6. Make sure that the foil pouch of the test cassette is undamaged and do not use damaged or dropped test cassettes.
7. Inadequate or improper collection, storage and handling of samples may lead to false test results.
8. Open and exposed test cassettes should not be used under a laminar flow header or in highly ventilated areas.
9. Bloody or excessively viscous samples should not be used.
10. Use the swab included in the kit to collect nasal swabs. The use of other swabs may lead to inaccurate results.
11. Pathogenic microorganisms such as hepatitis viruses and HIV may be found in clinical specimens. Standard precautions and institutional regulations should always be followed when working with, storing and destroying specimens and items contaminated with blood or other body fluids.
12. If the precautions are not observed, the test results are invalid.

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Test swab (sterile) - Please refer to the label of the swab for the CE of the swab.

Symbols used

Do not reuse	In vitro diagnosis
Store at room temperature	Follow directives
Description of the batch	Warning
Usable up to	Do not expose to light
Store in a dry place	Do not use if the packaging is damaged
Produced by...	Production date
Number of detections	Sterilisation with ethylene oxide
Order number	European conformity

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