Intended Use

The Novacheck SARS-CoV-2 rapid diagnostic test is an immunochromatographic per-patient test based on the sandwich principle, which contains two specific antibodies for qualitative detection of Nucleocapsid-protein antigen in human nasal swab samples. This test kit is used to detect the SARS-CoV-2 N-protein antigen that occurs in the acute phase of an infection.
An antigen is generally detectable in upper respiratory specimen during the acute phase of the infection (within the first 5 to 7 days from symptom onset).
The Novacheck SARS-CoV-2 rapid diagnostic test can be only used in symptomatic people for lay users. This test is only provided for use self testing for at-home testing. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.

Diagnostic Value

COVID-19 is an acute respiratory infection disease caused by The Novel Coronavirus SARS-CoV-2. The main transmission routes of infection are symptomatic and asymptomatic people who have been infected. Although the incubation period of the virus is up to 14 days, it is usually between 5 and 6 days. The main symptoms of the disease are loss of smell and taste, fever, weakness, fatigue and dry cough. In some cases, nasal congestion, shortness of breath, sore throat and myalgia are also observed.
Positive test results confirm the presence of SARS-CoV-2 antigens, but clinical history is also needed to determine the status of the infection. Positive results do not eliminate the possibility of bacterial infection or co-infection with other viruses.
Despite the negative test results, COVID-19 should not be completely ignored. Results should be evaluated together with recent exposure to the virus, medical history, presence of clinical signs and symptoms.

Test Working Principle

The Novacheck SARS-CoV-2 rapid diagnostic test is based on immunochromatographic polymer technology with the sandwich principle for qualitative detection of nucleocapsid protein antigen in human nasal swab samples. The sample is mixed with the colored polymer-labeled 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 there are SARS-CoV-2 antigens, they bind to the SARS-CoV-2 antibody 1. The mixture then binds to the immobile SARS-CoV-2 antibody 2 on the nitrocellulose membrane. The resulting antibody 1, antigen and antibody 2 complex form the colored test line. The control line of the test cassette is covered with secondary antibodies and gives a colored result if the test is performed normally.

Component

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

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

Storage and Shelf Life

Store between 2 °C - 30 °C, do not freeze, protect from light. Shelf life: 18 months.
Expiration date: See label.

Sample material

To avoid false or invalid results caused by for example sample contamination or inappropriate storing, the procedure should be performed right after sample collection.

The used test kit must be disposed of in accordance with local regulations.

Test Procedure

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

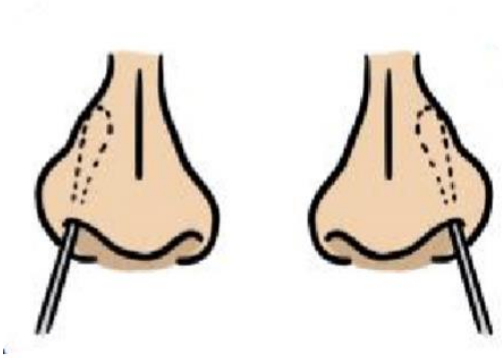
1. Please read the instructions carefully before using the test.

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

3. Nasal swabs are collected as illustrated bellow:

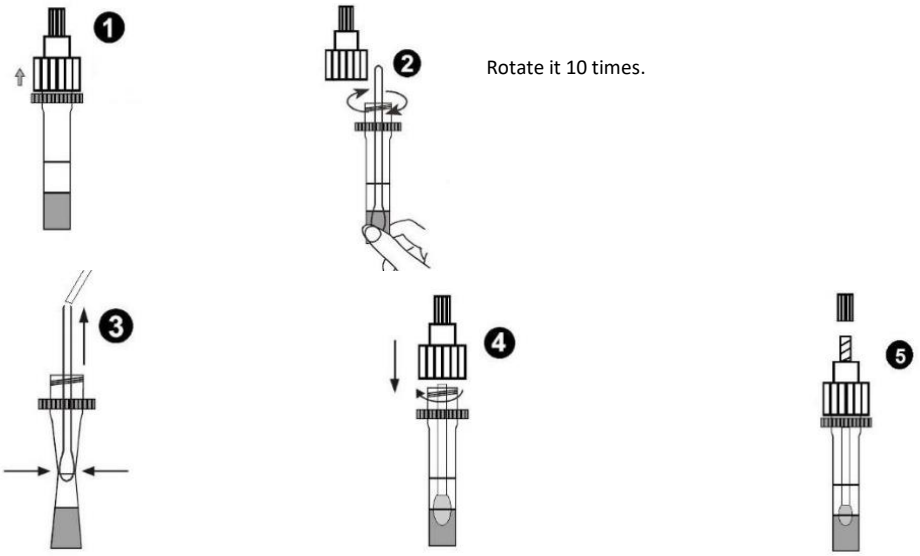
   Attention! Do not touch and dirt the sampling area of the swab.

   Insert the test swab approximately 2.5 cm into the nostril. Rotate the test swab five times on the inner surface of your nostril to collect mucus and cells. Repeat this procedure in the other nostril.



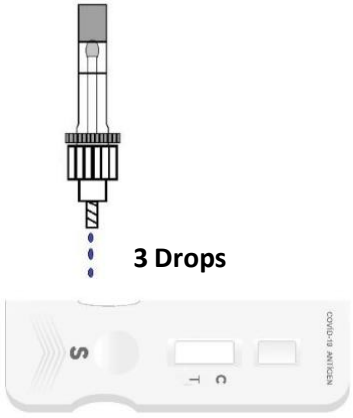
Preparation of sample solution:

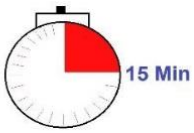
1. Remove the cover of the sample tube.
2. Place the test swab in the sample tube and rotate it at least 10 times.
3. Press the inserted tip firmly into the sample tube (with the sample). Break the test swab at the marked point without removing it.
4. Close the cap. Stir well by turning the tube or gently shaking it downwards.
5. Remove the small drip cap.



Applying the sample:

Keep the tip of the sample tube straight. Add 3 drops of sample solution by pressing the tube thoroughly into the test tray and wait for the result.





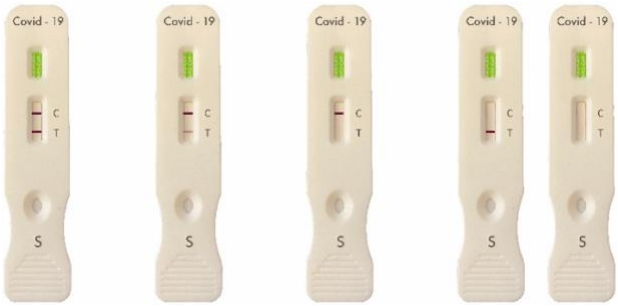
Read the result 15 minutes after applying the sample. Do not read the result after 20 minutes.

Interpretation of Test Results

Positive: A red line appears in both the control (C) and test line (T) area. Even if the red line is 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 visible only in the control (C) area, not in the test line (T) area. This means that the sample does not contain any SARS-CoV-2 antigen or that antigen concentrations are below the detection limit of the test.

Invalid: The test is invalid when the red line is not visible in the control (C) area.



positive weak positive negative invalid

Clinical performance*

The results of the Novacheck SARS-CoV-2 antigen test and PCR test are shown in the table below:

Summary of the Performance of the
SARS-CoV-2 Antigen Rapid Test Compared to RT-PCR

Candidate 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%.

Specifity = 99,9%； 95% CI: 99.26%～100.00%.

*It was examined in parallel with diagnostic PCR and antigen tests on 342 people who had positive symptoms of Covid-19 within seven (7) days of the onset of symptoms.

Limit of detection: 1.7×10^2 TCID50/mL
The detection limit was determined using positive samples diluted with the sample matrix of nasal swabs.

Hook Effect
Test results of this product showed no Hook effect for 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 has been tested using several microorganisms and viruses. No cross-reactivity was detected with specified concentrations of the following viruses and microorganisms:

Name	Concentration	Test Results
Influenza B/Y amagata	1.00×10^2 TCID50/mL	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	1.00×10^5 CFU/mL	Negative
Escherichia coli	1.00×10^5 CFU/mL	Negative
Haemophilus influenzae	1.20×10^6 CFU/mL	Negative
Mycobacterium binding	1.00×10^5 CFU/mL	Negative
Mycoplasma Pneumoniae	1.00×10^6 CFU/mL	Negative
Neisseria meningococcus	1.00×10^5 CFU/mL	Negative
Neisseria gonorrhoeae	1.00×10^5 CFU/mL	Negative
Pseudomonas aeruginosa	3.70×10^6 CFU/mL	Negative
Staphylococcus aureus	2.20×10^6 CFU/mL	Negative
Streptococcus pneumoniae	1.00×10^6 CFU/mL	Negative

Streptococcus pyogenes	1.28×10^6 CFU/mL	Negative
Streptococcus salivarius	1.00×10^5 CFU/mL	Negative

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

Interacting substance name	**Concentration**	**Negative interaction result**	**Positive interaction result**
Mucin	5%	Negative	Positive
Whole blood	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
Flunisolide	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 verification process

1. The content of this kit is used for the qualitative detection of SARS CoV-2 antigene from nasal swabs.
2. A negative test result may occur if the antigen level in a sample is below the detection limit of the test, or if the sample has not been properly collected/stored.
3. Errors in the implementation of the test may affect test performance and/or invalidate the test result.
4. The test results should be interpreted in connection with other clinical data presented to the physician.
5. Positive test results do not eliminate 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, if necessary, confirmed by a clinical molecular test, including infection control.
8. Clinical performance is evaluated with frozen samples, and performance may vary with fresh samples.
9. Sample stability recommendations are based on stability data from the influenza test, and performance may vary according to SARS-CoV-2. Sample should be tested right 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 diagnosis) has been evaluated for use only with human samples.
12. The clinical evaluation study was conducted with only symptomatic subjects with suspected SARS-CoV-2 infection. Consequently, the performance of the test may be reduced in asymptomatic subjects due to the lower amount of virüs material in the sample. Therefore, test for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing. The background is that the probability of detecting SARS-CoV-2 infection in asymptomatic individuals with this test increases until the day of disease onset.
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 diagnostic test is not specified for the function of identification/verification of tissue culture isolates and should not be used in this function.

Safety Directives

1. Suitable for use only for human in-vitro diagnosis.
2. Please read all operating instructions before testing.
3. Do not use reagents that have expired.
4. In case of contact with skin or eyes of the sample extraction solution, flush with plenty of water.
5. All components are single use only.
6. Ensure that the foil bag 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 incorrect test results.
8. Open and exposed test cassettes should not be used under a laminar flow header or in heavily ventilated areas.
9. Bloody or excessively viscous samples should not be used.
10. Use the swab inside the kit to take nasal swabs. Using other swabs may produce inaccurate results.
11. Pathogenic microorganisms such as hepatitis viruses and HIV can be found in clinical samples. Standard precautions and institutional regulations should always be followed when working with, storing and destroying all samples and items contaminated with blood or other bodily fluids.
12. If the precautions are not followed, the test results are not valid.

CE **1434**

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Test swab (sterile) - For CE of swab please refer to swab label.

Symbols used

Do not reuse	In Vitro Diagnosis
Store at room temperature	Follow Directives
Batch description	Warning
Usable up to	Do not expose to light
Store in a dry place	Do not use if package damaged
Produced by...	Production Date
Number of Detections	Sterilization with ethylene oxide
Order number	European Conformity

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Version: 04
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