

## INSTRUCTION FOR USE

### INTRODUCTION

In December 2019, the novel respiratory disease (COVID-19) caused by the coronavirus (SARSCoV-2) was reported in Wuhan, China.<sup>1,2</sup> According to WHO, most of the people infected with SARS-CoV-2 have mild to moderate respiratory diseases, fever, cough and recover without treatment. However, people with weak immune systems, such as the elderly or people with previous illnesses (e.g. cardiovascular disease, diabetes, chronic respiratory diseases, cancer, etc.) are more likely to develop a serious illness that can lead to the death of the infected person.<sup>3</sup>

This rapid test kit is intended for the qualitative detection of SARS-CoV-2 viral nucleocapsid antigens from anterior nasal secretion from individuals suspected of COVID-19. Positive result of the antigen test can be used for early isolation of patients with suspected infection, but it cannot be used as diagnosis basis of SARS-CoV-2 infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment. Further nucleic acid detection should be carried out for suspected population whose antigen test result is positive or negative.

This kit is an immunochromatography assay which detects SARS-CoV-2 nucleocapsid antigen in the samples with the help of the double antibody sandwich method. If there is virus antigen presence in the sample, it binds with the corresponding colloidal gold antibody. This complex "migrates" across the membrane and binds to the monoclonal antibody at the Test line (T). This creates a visible red line, which indicates a positive result. However, if the sample does not contain any antigen, then the complex cannot be formed and thus no reddish line forms in the Test line (T). Regardless of whether the sample contains antigen or not, a reddish line forms in the Control line (C).

### KIT COMPONENTS

- 1 Test cassette (SARS-CoV-2 Ag)
- 1 Sample tube with prefilled sample extraction buffer
- 1 Swab
- 1 Instruction for use

Additionally required materials:

- 1 timer

### TEST PREPARATION

Let test cassette and test components stand at a room temperature (15°C to 27°C) before performing the test. Lay all the supplied materials on a clean, dry and flat surface.

### TEST PERFORMANCE

Read the instructions for use completely before performing the test. A step-by-step instruction is given on the next page and describes the test procedure.

### EVALUATION OF TEST RESULTS

To read the test results simply determine whether a line is present or absent at the Control (C) position. It does not matter how strong or weak a Control line (C) is.

## PERFORMANCE CHARACTERISTICS

### 1. Sensitivity and Specificity

SARS-CoV-2 Antigen Rapid Test		RT-PCR		Total
		Positive	Negative	
Positive	Positive	146	1	147
	Negative	4	149	153
Total		150	150	300

Sensitivity: 97.33% (93.31%-99.27%)\*  
Specificity: 99.33% (96.34%-99.98%)\*  
Total consistent: 98.33% (96.15%-99.46%)\*

\*95 % Confidence Interval

### 2. Limit of detection:

LOD concentration	30 TCID <sub>50</sub> /mL
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### 3. Cross-reactivity

No cross-reaction was observed with following potential pathogens and NanoRepro SARS-CoV-2 Antigen Rapid Test:

Potential pathogens	concentration	cross-reactivity (Yes/No)
Human Coronavirus 229E (heat inactivated)	1.0 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Human Coronavirus OC43	1.0 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Human Coronavirus NL63	1.0 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Adenovirus	1.0 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Human Metapneumovirus	1.0 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Parainfluenza virus 1	1.0 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Parainfluenza virus 2	1.0 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Parainfluenza virus 3	5.2 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Parainfluenza virus 4	1.6 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Influenza A	2.5 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Influenza B	2.9 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Enterovirus	4.0 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Respiratory syncytial virus	4.0 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Rhinovirus	1.1 x 10 <sup>6</sup> PFU/mL	No
SARS-coronavirus	4.5 x 10 <sup>6</sup> PFU/mL	No
MERS-coronavirus	1.5 x 10 <sup>6</sup> TCID <sub>50</sub> /mL	No
Haemophilus influenza	1.4 x 10 <sup>6</sup> CFU/mL	No
Streptococcus pneumoniae	1.0 x 10 <sup>6</sup> CFU/mL	No
Streptococcus pyogenes	1.6 x 10 <sup>6</sup> CFU/mL	No
Candida albicans	1.8 x 10 <sup>6</sup> CFU/mL	No
Pooled human nasal wash	100%	No
Bordetella pertussis	1.4 x 10 <sup>6</sup> CFU/mL	No
Mycoplasma pneumoniae	1.0 x 10 <sup>6</sup> CFU/mL	No
Chlamydia pneumoniae	1.0 x 10 <sup>6</sup> CFU/mL	No
Legionella pneumophila	1.0 x 10 <sup>6</sup> CFU/mL	No

### 4. Interfering

Common interfering substances in the sample, such as blood, mucin, and pus, have no effect on the test results.

## WARNINGS AND IMPORTANT INFORMATION

- This kit is a qualitative detection, which cannot determine the exact content of antigen.
- The test is intended for use outside the body only.
- Not to be taken internally. Avoid sample buffer contact with skin and eyes.
- Keep out of the reach of children. Any child under age 18 shouldn't perform the test without parental guidance, or professional aid.
- Protect from sunlight, do not freeze. Store in a dry place between 2°C und 30°C. Do not use after the expiration date printed on the package.
- Not following the exact instructions can affect the outcome of the test. The final diagnosis must be confirmed by a physician.
- Do not use the test if the packaging is damaged. Do not use broken test components.
- All test components are only intended to be used for this test. Do not reuse the test or test components.
- The test should be carried out immediately or within one hour after opening the foil pouch (20-30°C, humidity <60%).
- Samples be processed as soon as possible after sample collection. If the test cannot be performed immediately, the sample should be stored in a sealed state, stored at 2-8°C for 8 hours, and stored below -20°C for 1 month. Long-term storage is not recommended.
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
- Refer to the local regulation in force regarding the disposal of the test components.
- A negative result does not rule out the infection of a SARS-CoV-2 infection. Therefore, the test should not be used as the only reference for the clinical diagnosis. The result must be confirmed by the PCR.
- The test is not validated on specimens from pregnant women.

## LITERATURE

- 1.) Nanshan Chen\*, Min Zhou\*, Xuan Dong\*, Jieming Qu\*, Fengyun Gong, Yang Han, Yang Qiu, Jingli Wang, Ying Liu, Yuan Wei, Jia'an Xia, Ting Yu, Xinxin Zhang, Li Zhang Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. LANCET. January 29, 2020.
- 2.) World Health Organization (Coronavirus disease 2019) [https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-\(covid-2019\)-and-the-virus-that-causes-it](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it) (Zugriff am 27.03.2020)
- 3.) World Health Organization (Coronavirus disease 2019) [https://www.who.int/health-topics/coronavirus#tab=tab\\_1](https://www.who.int/health-topics/coronavirus#tab=tab_1) (Zugriff am 27.03.2020)

**Note:** This product has received special approval from BfArM (No. 5640-S-096/21) according to Section 11 (1) MPG and therefore, can be placed on the market in Germany for a limited period of time.

## INSTRUCTIONS OF SYMBOL

Manufacturer	LOT Batch number (see imprint on package)
Consult instruction for use	for single use
Contains sufficient for 1 tests	Store at 2°C - 30°C Do not freeze.
Order number	In vitro diagnostic medical device (for external use)
Expire date (see imprint on package)	Keep dry
manufacturing date	

## STEP-BY-STEP-INSTRUCTION

### 1

Open the sealed pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.

### 2

Gently, insert the entire absorbent tip of the swab (around 1.5 cm) into your nostril. Slowly, rotate the swab in a circular against the inside walls of your nostril 5 times or more. Be sure to collect any nasal drainage that maybe present on the swab. Gently remove the swab. Use the same swab to repeat steps in the other nostril and slowly, take out the swab.

### 3

Take sample tube with prefilled sample extraction buffer and remove the white cap of the sample tube. Insert the swab into the sample tube prefilled with extraction buffer. Mix well and squeeze the swab 10-15 times by compressing the walls of the tube against the swab. Roll the swab head against the inner wall of the tubes as you remove it. Try to release as much liquid as possible. Dispose of the used swab in accordance with your local regulations.

### 4

Close the cap of the sample tube. Add 3 full drops of the mixed solution vertically into the sample well (S) of the test cassette. Read the result 15-20 minutes after adding the sample. Result got after 20 minutes is invalid.

### 5

**Positive**  
Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).  
The test result means that SARS-CoV-2 antigen are detectable in your sample. The detection of these antigens indicates with a high probability of infection with the novel coronavirus.  
**Please stay at home and contact your physician or the responsible health authority immediately to get information on how to proceed further.**  
**\*Note:** The thickness of the line is insignificant; any reddish color in the Test line (T) should be considered a positive result. The positive test result must be confirmed by PCR.

**Negative**  
Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).  
The test result indicates that there is no or too little SARS-CoV-2 Antigen in the sample and at the current time there is probably no infection with the novel coronavirus.  
**A negative result does not preclude SARS-CoV-2 infection, so please stay at home if you have clinical symptoms or if you have a well-founded suspicion and contact physician or responsible health authority to get information on how to proceed further.**  
False negative results can be from incorrect sampling, incorrect execution of the test, or insufficient virus in the sample.

**Invalid**  
If there is no Control line (C) or only a Test line (T) in the result window, the test did not run correctly and the results are not valid.  
It is important that you carefully follow the instructions for the test. You should test again with a new sample and a new test.