EN LABNOVATION

SARS-CoV-2 Antigen Rapid Test Kit

(Immunochromatography)

Self-test for Use at Home

INSTRUCTION FOR USE

INTRODUCTION

In December 2019, the novel respiratory disease (COVID-19) caused by the coronavirus (SARS-CoV-2) was reported in Wuhan, China.1,2 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.[3]

This rapid test kit is intended for the qualitative detection of SARS-CoV-2 viral nucleocapsid antigens from human anterior nasal of 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

Package Size	Components
1 Test/Kit	1 Test cassette 1 Sample tube with prefilled sample extraction buffer 1 Swab 1 Tube stand 1 Instruction for use
5 Tests/Kit	5 Test cassettes 5 Sample tubes with prefilled sample extraction buffer 5 Swabs 1 Tube stand 1 Instruction for use
20 Tests/Kit	20 Test cassettes 20 Sample tubes with prefilled sample extraction buffer 20 Swabs 1 Tube stand 1 Instruction for use

Additionally required materials:

1 Timer

TEST PREPARATION

Let test cassette and test components stand at a room temperature (15℃ to 27℃) before performing the test.

Lay all the supplied materials on a clean, dry and flat surface.

STORAGE & SHELF LIFE

The product should be stored at 2-30°C, and its shelf life is 24 months.

The test cassette and sample extraction buffer should be used immediately after opening.

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

The clinical performance characteristics of the SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) were verified by 560 samples of nasal swabs. According to the requirements in the instructions for use, collect, store and test the nasal swabs. At the same time, collect the nasopharyngeal swab specimen for nucleic acid (Vitassay qPCR SARS-CoV-2) detection.

The clinical comparison results of Labnovation SARS-CoV-2 Antigen Rapid Test Kit and PCR reference reagent are as follows:

SARS-CoV-2 Antigen Rapid Test	RT-PCR		TOTAL
	Positive	Negative	
Positive	105	0	105
Negative	5	450	455
TOTAL	110	450	560

Sensitivity: 95.45 %* (89.71% - 98.51%)

Specificity: 100.00 %* (99.18% - 100.00%)

Total accuracy: 95.68%* (93.65% - 97.21%)

*95 % Confidence Interval.

2. Limit of detection

LOD concentration	30 $TCID_{50}$/mL

3. Cross-reactivity

Tested with reference products, no cross-reactions were found to the following pathogens:

Potential Cross-Reacting Organism	Concentration Tested	Test Result
Human coronavirus 229E (heat inactivated)	1.0 x 105 U/mL	Negative
Human coronavirus OC43	1.0x105 TCID50/mL	Negative
Human coronavirus NL63	1.0x105 TCID50/mL	Negative
Adenovirus	1.0x105 TCID50/mL	Negative
Human Metapneumovirus	1.0x105 TCID50/mL	Negative
Parainfluenza virus 1	1.0x105 TCID50/mL	Negative
Parainfluenza virus 2	1.0x105 TCID50/mL	Negative
Parainfluenza virus 3	5.2x105 TCID50/mL	Negative
Parainfluenza virus 4	1.6 x 104 TCID50/mL	Negative
Influenza A	2.5 x 105 TCID50/mL	Negative
Influenza B	2.9 x 105 TCID50/mL	Negative
Enterovirus	4.0 x 105 TCID50/mL	Negative
Respiratory syncytial virus	4.0 x 105 TCID50/mL	Negative
Rhinovirus	1.1 x 105 PFU/mL	Negative
MERS-coronavirus	1.5 x 105 TCID50/mL	Negative
Haemophilus influenza	1.4 x 106 CFU/mL	Negative
Streptococcus pneumoniae	1.0 x 106 CFU/mL	Negative
Streptococcus pyogenes	1.6 x 106 CFU/mL	Negative
Candida albicans	1.8 x 106 CFU/mL	Negative
Pooled human nasal wash	100%	Negative
Bordetella pertussis	1.4 x 106 CFU/mL	Negative
Mycoplasma pneumoniae	1.0 x 106 CFU/mL	Negative
Chlamydia pneumoniae	1.0 x 106 IFU/mL	Negative
Legionella pneumophila	1.0 x 106 CFU/mL	Negative

4. Interfering

The following interfering substances commonly found in the sample, such as blood, mucin, and pus, have no effect on the test results.

Active Ingredient	Concentration	Positive Reference Result	Negative Reference Result
Whole Blood	1.2 % v/v	Positive	Negative
Mucin	2.0 % w/v	Positive	Negative
Sodium Chloride	5% v/v	Positive	Negative
Fluticasone Propionate	0.3 ng/mL	Positive	Negative
Gluconic Acid Zinc	5 % w/v	Positive	Negative
Fluconazole	5 % w/v	Positive	Negative
Oxymetazoline	12 % v/v	Positive	Negative
Cromolyn	15 % v/v	Positive	Negative
Phenol	15 % v/v	Positive	Negative
Benzocaine, Menthol	0.15% w/v	Positive	Negative
Tamiflu (Oseltamivir Phosphate)	1.3 mg/mL	Positive	Negative
Ribavirin	12.9 mg/mL	Positive	Negative
Tobramycin 4.0	4.0 ug/mL	Positive	Negative

WARNINGS AND IMPORTAN 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.
- Protect from sunlight, do not freeze. Store in a dry place between 2°C and 30°C. Do not use after the expiration date printed on the package.
- Keep out of the reach of children. Any child under age 18 shouldn't perform the test without parental guidance, or professional aid.
- 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 (15-30°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.

• DISPOSAL The test kit can be disposed of with normal household waste in accordance with applicable local regulations.

• 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.

• After use, rinse hands or, in case of contact with the buffer solution, the affected body parts thoroughly with water.

• If symptoms persist: Seek medical advice.

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.

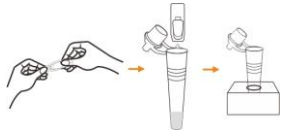
2.) World Health Organization (Coronavirus disease 2019) https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it(Zugriff am 27.03.2020)

3.) World Health Organization (Coronavirus disease 2019) https://www.who.int/health-topics/coronavirus# tab=tab_1 (Zugriff am 27.03.2020)

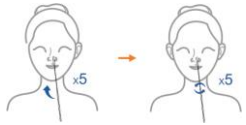
STEP-BY-STEP INSTRUCTION

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

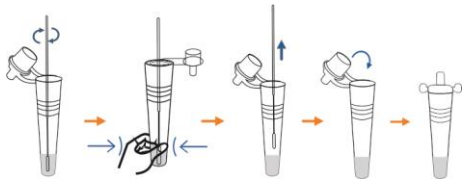
❷Unpack the Sample extraction, add all of sample extraction into the sample tube and then put the tube into tube stand.



❸Gently, 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.



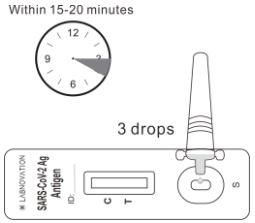
❹ Take the sample tube with sample extraction. Insert the swab into the sample tube with extraction buffer. Mix well. Mix well and squeeze the swab 10-15 times by compressing the walls of the tube against the swab. Roll the swab head against the inner wall of the tubes as you remove it. Try to release as much liquid as possible. Dispose of the test kit with normal household waste in accordance with applicable local regulations.



❺ 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.



⚠	Keep out of the reach of children. Any child under age 18 shouldn't perform the test without parental guidance, or professional aid.
☣	Improper handling of specimen can lead to biological infections. Avoid any direct contact with reagents or wastes.

INTERPRETATION OF RESULTS

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 is detectable in your sample. The detection of these antigens indicates with a high probability of infection with the novel coronavirus.

In case of a positive test result:

- There is currently a suspicion of a COVID-19 infection.

- Immediately contact a doctor/family physician or the local public health department

- follow local guidelines for self-isolation

- have a PCR confirmatory test performed

***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.

If the test result is negative

- Continue to follow all applicable rules regarding contact with others and protective measures.

- Even if the test is negative, an infection may still be present.

- In case of suspicion, repeat the test after 1 - 2 days, as the coronavirus cannot be detected accurately in all phases of an infection.

***Note:** 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.

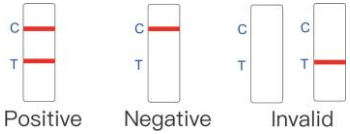
In case of an invalid test result

- Possibly caused by incorrect test performance

- Repeat the test

- If test results remain invalid, contact a doctor or a COVID-19 testing centre.

***Note:** It is important that you carefully follow the instructions for the test. You should test again with anew sample and a new test.



DISPOSE USED TEST

All used test components should be put into the bio safety bag before being disposed in the trash.

***Note:** After completing all steps, wash hands or use hand sanitizer.

MANUFACTURER

LABNOVATION TECHNOLOGIES, INC.

Address: 101 and 5th Floor, Building 1, No. 68, 18th Road, Guangming Hi-Tech Park, Tangjia Community, Fenghuang Street, Guangming District, Shenzhen 518107, China

Tel: 0086-755-86368398 Web: www.labnovation.com

E-mail: export@labnovation.com

CE 1434 EC REP MedNet EC-REP GmbH Borkstrasse 10,48163 Muenster,Germany

Hotline: +49 251 3226669

Swabs MANUFACTURER

Shenzhen KangDaAn Biological Technology co., LTD

East-1, 3rd floor, Building 2, Shunheda factory, Liuxiandong industrial zone, Xili street, Nanshan district, Shenzhen

CE 0197 EC REP Share Info Consultant Service LLC Repräsentanzbüro Heerdter Lohweg 83, 40549 Düsseldorf

INSTRUCTIONS OF SYMBOL

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

Ref Ver.V1.0

2021-11-30