COVID-19 Antigen Rapid Test Kit
Instructions For Use

PRODUCT NAME

COVID-19 Antigen Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

This product is used for in vitro qualitative detection of the antigen of novel corona-virus in human nasal swabs or throat swab specimens. The detection is based on the antibodies which were developed specifically recognizing and reacting with the nucleoprotein of Novel Corona-virus. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infection.

The novel corona-viruses belong to the β genus.COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel corona-virus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days.The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

This kit uses immunochromatography for detection. The specimen will move forward along the test card under capillary action. If the specimen contains a novel corona-virus antigen, the antibody will bind to the colloidal gold-labeled new corona-virus monoclonal antibody. The immune complex will be membrane fixed will be corona-virus monoclonal antibody capture, form the fuchsia line, display will be corona-virus antigen positive; If the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line.

KIT COMPONENTS

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched.
2. Extraction Tubes (with Caps): 20 pieces filled 200 ul extraction solution.
3. Work Stations: 2 paper work stations as folded.
4. Instructions For Use: 1 copy attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. COIVD-19 antigen rapid test is intended for *in vitro* diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of extraction Solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate swab, tube and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix extraction Solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 15 minutes incubation time following the addition of extracted solution. Do not read results beyond 20 minutes.

STORAGE INSTRUCTIONS

1. The kit and extraction solution should be stored between 2-30°C and the shelf life is 24 months.
2. Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the extraction Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SPECIMEN COLLECTION

1. Nasopharyngeal swab sample
   Insert a sterilized swab into a nasal cavity securely from a nostril and collect mucoepidermis wiping turbinate several times.
2. Pharyngeal swab sample
   Insert a sterilized swab into pharynx and collect mucoeoidermis mainly wiping flare region of post-pharyngeal wall and palatine tonsil several times, and be careful not to make saliva attach to the swab.

The clinical samples should be tested immediately after collection, otherwise the samples must be sealed in individual dry container but no longer than 8 hours under room temperature. It is recommended to collect sample from Nasopharyngeal for more accurate results.

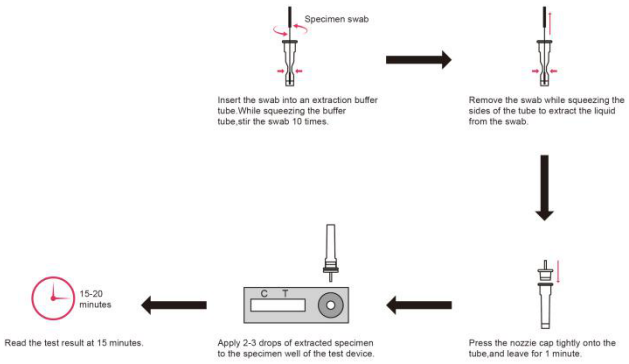
TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

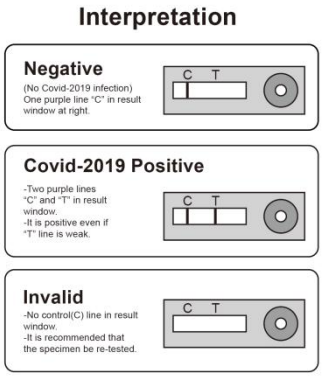
1. Remove the test device from the sealed foil pouch and use it as soon as possible. Place the

test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

2. Place the extraction tube on the work station.Put the swab specimen into the extraction tube, rotate the swab for about 10 times, and press the swab head against the tube wall to release the antigen in the swab. Squeeze the swab over the head to remove the swab so as to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
3. Install the dropper cap on the extraction tube and leave for 1 minute, then put 2 to 3 drops into the specimen hole of the test card, start the timer.
4. Read the results at 15 minutes, and the results after 20 minutes are no longer valid.



INTERPRETATION OF RESULTS



Negative result: if there is only a quality control line C, the detection line is colorless, indicating that novel corona-virus antigen has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the novel corona-virus antigen has been detected and the result is positive for antigen.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure above), and the test shall be conducted again.

LIMITATIONS

1. The kit is for professional in vitro diagnostic use only. The test should be used for the detection of novel corona-virus in nasal swab or throat swab specimens. Neither the quantitative value nor the rate of increase in novel corona-virus concentration can be determined by this qualitative test.
2. The kit will only indicate the presence of novel corona- virus in the specimen or not.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the novel corona-virus present in the nasal/throat swab is not adequate or is below the detectable level of the test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
8. A positive result for novel corona-virus does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and PCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

Nasal swabs		PCR		Total Results
Antigen Rapid Test	Results	Positive	Negative	
	Positive	89	11	100
	Negative	2	221	223
Total Results		91	232	323
Throat swab		PCR		Total Results
Antigen Rapid Test	Results	Positive	Negative	
	Positive	75	16	91
	Negative	3	184	187
Total Results		78	200	278

Clinical sensitivity = (89+75)/(89+2+75+3)=97.04% (95%CI* 93.23% to 99.03%)

Clinical specificity = (221+184)/(221+11+184+16)=93.75 % (95%CI* 91.04% to 95.84%)

Accuracy: (89+75+221+184)/ (89+2+75+3+221+11+184+16) =94.68% (95%CI* 92.57% to 96.33%)

Minimum detection limit

The minimum detection limit for The kit is 200 $TCID_{50}$/ml.

Interference Substances

The following potential interfering substances have been tested using The kit and no interference was observed:

Substance	Concentration
~~Whole Blood~~	~~1% (v/v)~~
~~Dexchlorpheniramine hydrochloride~~	~~10% (v/v)~~
Budesonide	10% (v/v)
Oseltamivir Phosphate	10mg/ml
Ceftriaxone sodium	1mg/ml
Azithromycin	1mg/ml
Meropenem	1mg/ml
Vancomycin hydrochloride	1mg/ml
Levofloxacin Hydrochloride	1mg/ml
Paracetamol	30μg/ml
Aspirin	50μg/ml
Doxycycline Hydrochloride	30μg/ml
Phenylephrine Hydrochloride	10% (v/v)
Ibuprofen	500μg/ml
Mupirocin Ointment	1mg/ml
Tobramycin	5μg/ml
Erythromycin Lactobionate	100μg/ml
Ciprofloxacin Hydrochloride	10μg/ml
Sodium Cromoglicate	2mg/ml
Mometasone Furoate Aqueous	0.5% (v/v)
Triamcinolone Acetonide Acetate	1% (v/v)

Cross Reaction

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Virus/Bacteria/Parasite	Strain	Concentration
MERS-coronavirus	N/A	72 μg/ml
Adenovirus	Type 1	1.5 x$10^6$$TCID_{50}$/ml
	Type 3	7.5 x$10^6$$TCID_{50}$/ml
	Type 5	4.5 x$10^6$$TCID_{50}$/ml
	Type 7	1.0 x$10^6$$TCID_{50}$/ml
	Type 8	1.0 x$10^6$$TCID_{50}$/ml

	Type 11	2.5 x$10^6$$TCID_{50}$/ml
	Type 18	2.5 x$10^6$$TCID_{50}$/ml
	Type 23	6.0 x$10^6$$TCID_{50}$/ml
	Type 55	1.5 x$10^6$$TCID_{50}$/ml
Influenza A	H1N1 Denver	3.0 x$10^8$$TCID_{50}$/ml
	H1N1 WS/33	2.0 x$10^8$$TCID_{50}$/ml
	H1N1 A/Mal/302/54	1.5 x$10^8$$TCID_{50}$/ml
	H1N1 New Caledonia	7.6 x$10^8$$TCID_{50}$/ml
	H3N2 A/Hong Kong/8/68	4.6 x$10^8$$TCID_{50}$/ml
Influenza B	Nevada/03/2011	1.5 x$10^8$$TCID_{50}$/ml
	B/Lee/40	8.5 x$10^8$$TCID_{50}$/ml
	B/Taiwan/2/62	4.0 x$10^8$$TCID_{50}$/ml
Respiratory syncytial virus	N/A	2.5 x$10^8$$TCID_{50}$/ml
Legionella pneumophila	Bloomington-2	1 x 10^5PFU/ml
	Los Angeles-1	1 x 10^5PFU/ml
	82A3105	1 x 10^5PFU/ml
Rhinovirus A16	N/A	1.5 x$10^6$$TCID_{50}$/ml
Mycobacterium tuberculosis	K	1 x 10^5PFU/ml
	Erdman	1 x 10^5PFU/ml
	HN878	1 x 10^5PFU/ml
	CDC1551	1 x 10^5PFU/ml
	H37Rv	1 x 10^5PFU/ml
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	1 x 10^5PFU/ml
	178 [Poland 23F-16]	1 x 10^5PFU/ml
	262 [CIP 104340]	1 x 10^5PFU/ml
	Slovakia 14-10 [29055]	1 x 10^5PFU/ml
Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF130]	1 x 10^5PFU/ml
Mycoplasma pneumoniae	Mutant 22	1 x 10^5PFU/ml
	FHstrainofEatonAgent[NCTC101 19]	1 x 10^5PFU/ml
	36M129-B7	1 x 10^5PFU/ml
Coronavirus	229E	1.5 x$10^6$$TCID_{50}$/ml
	OC43	1.5 x$10^6$$TCID_{50}$/ml
	NL63	1.5 x$10^6$$TCID_{50}$/ml
	HKU1	1.5 x$10^6$$TCID_{50}$/ml
Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002	1.5 x$10^6$$TCID_{50}$/ml
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	1.5 x$10^6$$TCID_{50}$/ml
Parainfluenza virus	Type 1	1.5 x$10^6$$TCID_{50}$/ml
	Type 2	1.5 x$10^6$$TCID_{50}$/ml
	Type 3	1.5 x$10^6$$TCID_{50}$/ml
	Type 4A	1.5 x$10^6$$TCID_{50}$/ml

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use,Please don't reuse it
	Use-by date		Consult instructions for use

	Cautions		Manufacturer
2°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
CE	CE mark		Biological risks
EC REP	European Authorized Representative		

Hangzhou Frenovo Biotech Co., Ltd.
Address: Room 401,Building 36,No.488-1,Donghu North Road, Donghu Community, Yuhang District, Hangzhou City, Zhejiang Province, China.
Tel: 86-0571-89170657
Email: business@frenovobio.com

EC REP **Lotus NL B.V.**
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Email: peter@lotusnl.com

INSTRUCTION APPROVAL AND REVISION DATE

Revision Date:
Date of Issue: