Novel Coronavirus (COVID-19) Antigen Detection Kit

(Latex Immunochromatography)

Instruction for Use

【Product name】

Novel Coronavirus (COVID-19) Antigen Detection Kit (Latex Immunochromatography)

【Size】

1 test, 5 tests, 10 tests, 25 tests, 50 tests.

【Intended use】

This product is used for in vitro qualitative detection of the antigen of novel coronavirus (COVID-19) N protein in human nasopharyngeal swab and oropharyngeal swab.

【Principle of test】

This kit uses latex immunochromatography and double antibody sandwich immunoassay to detect the novel coronavirus (COVID-19) antigen in nasopharyngeal swab and oropharyngeal swab. Drip the sample to the designated area of the test card. By the chromatography effect, a reaction complex is formed when the novel coronavirus (COVID-19) antigen in the sample reacts with the latex microspheres labelled novel coronavirus (COVID-19) antibody on the binding pad. It moves forward along the nitrocellulose membrane. The detection line (T) shows red, should the complex be captured by the novel coronavirus (COVID-19) antibody immobilized on the nitrocellulose membrane detection line (T). Detection line (T) is not showing red colour when there is no binding occurs, should there is no novel coronavirus (COVID-19) antigen in the sample. The quality control line (C) should be displayed in red regardless of whether the test substance is contained in the tested sample. Otherwise, the test is considered as invalid.

【Main components】

1. The main components of the test card: the test card is composed of a test strip shell and a test strip.
2. The main components on the test strip are:

a. Binding pad: contains latex microspheres labelled novel coronavirus (COVID-19) antibody.

b. Nitrocellulose membrane: novel coronavirus (COVID-19) antibody and goat anti-mouse IgG antibody is fixed in the detection area and the quality control area, respectively.

c. Sample pad

d. Absorbent paper

e. PVC bottom plate

No.	Items	1 Test pack	5 Tests pack	10 Tests pack	25 Tests pack	50 Tests pack
1	Test card（for one test）	1	5	10	25	50

2	Instruction for use	1	1	1	1	1
3	Sample extraction tube and dripper	1 set	5 sets	10 sets	25 sets	50 sets
4	Sample extraction buffer	1×0.5mL	1×0.5mL	10×0.5mL	25×0.5mL	50×0.5mL
5	Nasopharyngeal swab (Optional)	1	5	10	25	50
6	Oropharyngeal swab (Optional)	1	5	10	25	50

Accessories Required But Not Provided

(1)Tongue depressor

(2)Extraction tube holder

(3)Timer

(4)Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.

(5)Appropriate biohazard waste container and disinfectants

【Storage conditions & period of validity】

1. The kit should be stored at 2℃~30℃ with 18 months validity.
2. Avoid moisture, heat, and excessive force during storage.

【Sample requirement】

The test can be performed with oropharyngeal swab and nasopharyngeal swab specimen.

(1)According to standard nasopharyngeal swab or oropharyngeal swab specimencollection procedure.

(2) Nasopharyngeal swab specimen collection: Tilt patient's head back to 70 degrees. Insert swab into nostril (Swab should reach a depth equal to the distance from nostrils to outer opening of the ear). Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.

(3) Oropharyngeal swab specimen collection: Insert swab into the posterior pharynxand tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

【Test methods】

Please read this instruction carefully before use. Samples, reagents, and other required equipment should be used after been rested to room temperature, In the environment of 60% or greater humidity, the kit should be used immediately after opening the aluminium foil, otherwise use within one hour once package been opened.

1. Specimen extraction (see Figure 1)

(1). Add 1 Vial (0.35mL) sample extraction buffer to the extraction tube.

(2). Put the swab had collected specimen into the extraction tube, hold and press the swab head against the wall of tube with force while rotating the swab for about 10 times to release the antigen into the extraction solution from the swab head.

(3). Install the extraction tube cover to the extraction tube. The retained extract was taken for testing.

2. Testing procedures (see Figure 2)

(1). Open the aluminium foil bag and take out the test card lay flat.

(2). Drip 80μL (about 2~3 drops) of the processed sample extract to the sample hole of the test card.

(3). Wait for 15 minutes, read and interpret the test result. The test result should not be read and interpreted after 20 minutes.

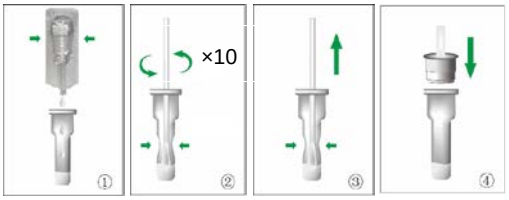


Figure 1

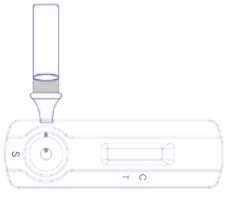


Figure 2

【Interpretation of test results】 (see Figure 3)

Positive: There are one clear red bar on each of the test line (T) and the quality control line (C), which indicates the novel coronavirus (COVID-19) antigen test is positive.

Negative: Only one clear red bar on the quality control line (C), which indicates the novel coronavirus (COVID-19) antigen test is negative.

Invalid: There is no red bar on the quality control line (C), and the test is invalid regardless of whether there is a red bar on the detection line (T).

Note: The colour saturation of the displayed results is related to the concentration of the tested substance in the extracted sample. Regardless of the colour saturation, the result should be interpretated according to whether the red bar(s) is displayed. This reagent contains a quality control process. A red bar must be presented on quality control line (C) to confirm the test result is valid.

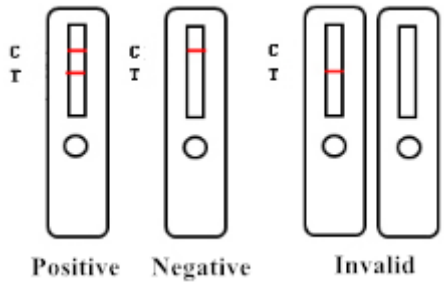


Figure 3

【Limitations of inspection methods】

1. This reagent is only for detecting respiratory secretions from nasopharyngeal and oropharyngeal swabs.
2. The accuracy of the test is great affected by the sample collection process. Improper sample collection and sample storage, stale sample or repeated freezing and thawing of samples will affect the test results.
3. The test card only provides qualitative detection of the COVID-19 antigen in the sample. Should you need to test the specific content of a certain index, please use relevant instruments.
4. The test result of this reagent is for clinical reference and is not used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in conjunction with their symptoms/signs, medical history, other laboratory tests and treatment responses.
5. Due to the methodological limitations of antigen-based test reagents, its analytical sensitivity is generally lower than that of nucleic acid-based reagents. Therefore, more attention should be given to negative results and needs to combine other test results for comprehensive diagnosis. It is recommended that negative results in doubt should be reviewed by performing nucleic acid testing.
6. Analysis of potential factors that cause the false negative results:
   i. Improper sample collection, operation and processing, and low virus titre in the sample may lead to false negative results.
   ii. Various gene mutations may cause changes in antigenic determinants, resulting in false negative results. This type of situation is more likely to occur with monoclonal antibody reagents.
   iii. The optimal sample type and the optimal sampling time after infection (peak virus titre) have not been verified. Therefore, multiple sample collections from different sites and time for the same patient may reduce the probability of false negatives result.

【Product performance index】

1. Minimum detection limit: 3 copies of the novel coronavirus (COVID-19) recombinant antigen reference material (L1~L3) should be tested. L1 should be negative, L2 and L3 should be positive.
2. Endogenous interfering substances: mucin ≤10g/L, blood ≤10%, pus ≤5%, will not interfere with the test results. Oxymetazoline ≤0.375mg/mL, Dexamethasone ≤2.5mg/L, Sulfur ≤50mg/mL, Zanamivir ≤1.25mg/L, Mupirocin ≤ 5mg/mL, Tobramycin ≤0.8 mg/L, will not interfere with the test results.
3. Cross-reaction: reaching the specified concentration, no cross-reaction with the following microorganisms:

Potential Cross-Reactant	Test Concentration	Potential Cross-Reactant	Test Concentration
Human coronavirus 229E (heat inactivated)	1.0 x 10^5 $TCID_{50}$/mL	Respiratory syncytial virus	1.0 x 10^5 $TCID_{50}$/mL
Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	Rhinovirus	1.0 x 10^5 $TCID_{50}$/mL
Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	HCoV-HKU1	10μg/mL
Adenovirus	1.0 x 10^5 $TCID_{50}$/mL	MERS-CoV Nucleoprotein	0.25ng/mL
Human Metapneumovirus	1.0 x 10^5 $TCID_{50}$/mL	Haemophilus influenza	1.5 x 10^6 CFU/mL
Parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/mL	Streptococcus pneumoniae	1.5 x 10^6 CFU/mL
Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL	Streptococcus pyogenes	1.5 x 10^6 CFU/mL
Parainfluenza virus 3	1.0 x 10^5 $TCID_{50}$/mL	Candida albicans	1.5 x 10^6 CFU/mL
Parainfluenza virus 4	1.0 x 10^5 $TCID_{50}$/mL	Bordetella pertussis	1.5 x 10^6 CFU/mL
Influenza A	1.0 x 10^5 $TCID_{50}$/mL	Mycoplasma pneumoniae	1.5 x 10^6 CFU/mL
Influenza B	1.0 x 10^5 $TCID_{50}$/mL	Chlamydia pneumoniae	1.5 x 106 CFU/mL
Enterovirus	1.0 x 10^5 $TCID_{50}$/mL	Staphylococcus epidermidis	1.5 x 106 CFU/mL
Staphylococcus aureus	1.5 x 106 CFU/mL	Legionella pneumophila	1.5 x 106 CFU/mL
Mycobacterium tuberculosis	1.5 x 106 CFU/mL	Pneumocystis jirovecii (PJP)	1.5 x 106 CFU/mL

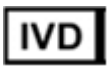
【Precautions】

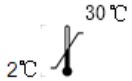
1. This kit is for in vitro diagnostic use only.
2. The test card, sample extraction tube and dripper, swab are all disposable and cannot be reused.
3. Please check the integrity and expiry date of the kit package before use. The kit been stored in fridge should be restored to ambient temperature prior opening the package. Kit with damaged package and/or the kit has passed expiry date cannot be used.
4. The components in the kits of different batch numbers are not interchangeable.
5. After the test card is taken out of the aluminium foil bag, the test should be carried out as soon as possible to avoid leaving it in the air for prolonged time, which may contract moisture.
6. Take adequate the personal safety measurements and due care while carrying out test.
7. The optimal detection temperature is 15℃ ~ 30℃, with 40% ~ 60% relative humidity.
8. The desiccant in the aluminium foil bag is not edible.
9. Should no red bar show on the quality control line (C), the test deemed to be invalid.
10. All specimens, reagents and potential contaminants should be disinfected and disposed in accordance with the relevant local regulations.

【Approval Date and Revision Date of the Instruction for use】

Approval Date: 15 July 2020
Revision Date: 26 May 2021
Date of Issue: 26 May 2021

【Index of CE Symbols】

	The product is used in vitro, please don’t swallow it.		Please don’t reuse it
	Validity		Please read the instruction book carefully before using
	Warning, please refer to the instruction in the annex		Manufacturer

	Temperature scope within which the product is reserved		Batch number
	European union authorization representative		Keep dry
	Avoid overexposure to the sun		Don’t use the product when the package is damaged
	Date of manufacture		Biological risks
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Tests per kit

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