

Technical Data Sheet

Product specification

1. Product info.	Name: SARS-CoV-2 Antigen Assay Kit (Immunochromatography) Model: 1test/kit,5tests/kit, 20tests/kit
2. Description	This product is used to qualitatively detect the novel coronavirus (SARS-CoV-2) antigen in human anterior nasal swabs .
3. Features	Our products have the characteristics of high sensitivity, good specificity and convenient operation.
4. Intended use	This product is used to qualitatively detect the novel coronavirus (SARS-CoV-2) antigen in human anterior nasal swabs . It can be used for rapid investigation of suspected novel coronavirus cases, and can also be used as a reconfirmation method for nucleic acid detection in discharged cases. A positive test result requires further confirmation, and a negative test result cannot rule out the possibility of infection. This kit is for home use by laymen in a non-laboratory setting (such as person's home or certain non-traditional sites such as offices, sporting events, airports, schools etc.). It is recommended to conduct a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests.

Technical information

	Component name	Material
1. List of Materials	Test card	nitrocellulose membrane
	Extraction tube	PE+PP
	Sample collection swab	PP
2. Latex free	Yes	
3. Characteristic	Sensitivity	96.77%
	Specificity	99.20%
	Accuracy(Total coincidence rate)	98.72%
	Minimum detection limit	When the virus content is greater

	than 400TCID ₅₀ /ml, the positive detection rate is greater than 95%. When the virus content is less than 200TCID ₅₀ /ml, the positive detection rate is less than 95%, so the minimum detection limit of this product is 400TCID ₅₀ /ml.
Precision	Three consecutive batches of reagents were tested for precision. Different batches of reagents were used to test the same negative sample 10 times in succession, and the results were all negative. Different batches of reagents were used to test the same positive sample 10 times in succession, and the results were all positive.
HOOK effect	When the virus content in the sample to be tested reaches 4.0*10 ⁵ TCID ₅₀ /ml, the test result still does not show the HOOK effect.

The test card of this product was tested with virus samples within the following concentration range, and the results showed that there was no cross-reaction.

No.	Name	Concentration	No.	Name	Concentration
1	HCOV-HKU1	10 ⁵ TCID ₅₀ /ml	17	H7N9	10 ⁵ TCID ₅₀ /ml
2	Staphylococcus aureus	10 ⁶ TCID ₅₀ /ml	18	H5N1	10 ⁵ TCID ₅₀ /ml
3	Group A streptococci	10 ⁶ TCID ₅₀ /ml	19	Epstein-Barr virus	10 ⁵ TCID ₅₀ /ml
4	Measles virus	10 ⁵ TCID ₅₀ /ml	20	Enterovirus CA16	10 ⁵ TCID ₅₀ /ml
5	Mumps virus	10 ⁵ TCID ₅₀ /ml	21	Rhinovirus	10 ⁵ TCID ₅₀ /ml
6	Adenovirus type 3	10 ⁵ TCID ₅₀ /ml	22	Respiratory syncytial virus	10 ⁵ TCID ₅₀ /ml
7	Mycoplasmal pneumonia	10 ⁶ TCID ₅₀ /ml	23	Streptococcus pneumoniae	10 ⁶ TCID ₅₀ /ml
8	Parainfluenzavirus, type 2	10 ⁵ TCID ₅₀ /ml	24	Candida albicans	10 ⁶ TCID ₅₀ /ml
9	Human metapneumovirus	10 ⁵ TCID ₅₀ /ml	25	Chlamydia pneumoniae	10 ⁶ TCID ₅₀ /ml
10	Human coronavirus OC43	10 ⁵ TCID ₅₀ /ml	26	Bordetella pertussis	10 ⁶ TCID ₅₀ /ml
11	Human coronavirus 229E	10 ⁵ TCID ₅₀ /ml	27	Pneumocystis jiroveci	10 ⁶ TCID ₅₀ /ml
12	Bordetella parapertussis	10 ⁶ TCID ₅₀ /ml	28	Mycobacterium tuberculosis	10 ⁶ TCID ₅₀ /ml

4. Cross-reactivity

13	Influenza B Victoria STRAIN	10 ⁵ TCID ₅₀ /ml	29	Legionella pneumophila	10 ⁶ TCID ₅₀ /ml
14	Influenza B YSTRAIN	10 ⁵ TCID ₅₀ /ml	30	MERS-coronavirus	10 ⁵ TCID ₅₀ /ml
15	Influenza A H1N1 2009	10 ⁵ TCID ₅₀ /ml	31	Human coronavirus NL63	10 ⁵ TCID ₅₀ /ml
16	Influenza A H3N2	10 ⁵ TCID ₅₀ /ml			

The test results do not be interfered with the substance at the following concentration:

No.	Name	Concentration	No.	Name	Concentration
1	Whole Blood	4%	9	Oseltamivir	5mg/ml
2	Ibuprofen	1mg/ml	10	Naphazoline Hydrochloride Nasal Drops	15%
3	tetracycline	3µg/ml	11	Mucin	0.5%
4	chloramphenicol	3µg/ml	12	Compound Benzoin Gel	1.5mg/ml
5	Erythromycin	3µg/ml	13	Cromolyn glycate	15%
6	Tobramycin	5%	14	Deoxyepinephrine hydrochloride	15%
7	menthol	15%	15	Afrin	15%
8	Mupirocin	10mg/ml	16	Fluticasone propionate spray	15%

5. Interference Substances

6. Sterilization method

Non-sterile

7. Shelf Life

18 months

8. Packaging specification

6.1 Sales unit

1、 5、 20

Per kit

REV

01

Date

04.14.2021