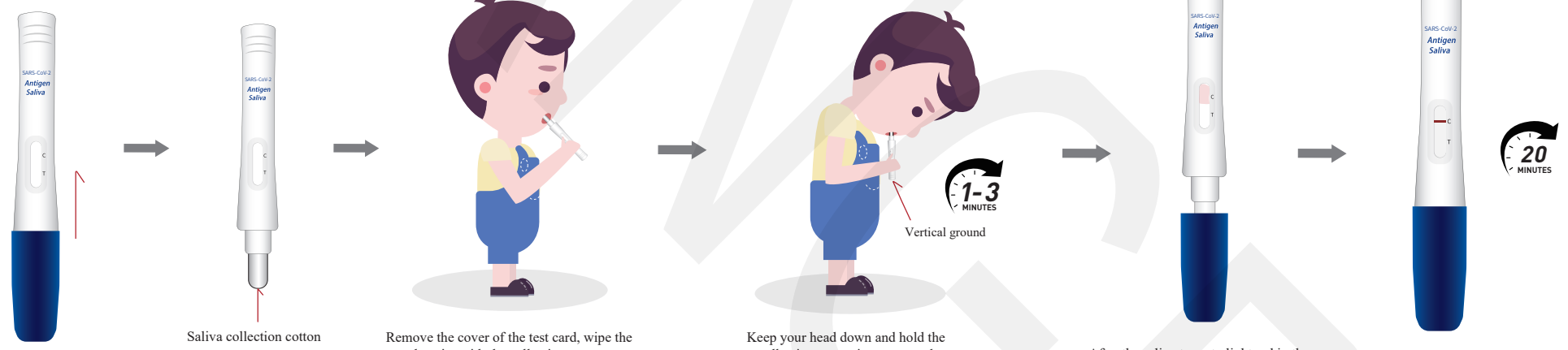
CE
IVD

SARS-CoV-2 Antigen Detection Kit（Saliva）
Instruction for Use

【Product name】
SARS-CoV-2 Antigen Detection Kit（Saliva）
【Packing Specification】
1 Test/Box, 2 Tests/Box, 5 Tests/Box, 25 Tests/Box
【Type】
nCovAg-S
【Intended use】
This product is used for qualitative detection of covid-19 antigen in human saliva.For those with a history of exposure, but no symptoms and symptoms of coronavirus pneumonia disease, screening should be performed at the initial stage of symptoms (0 to 7 days) after infection.The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus 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.This product provides preliminary test results. A negative result does not preclude infection with a novel coronavirus and is not used as the sole basis for treatment or other management decisions.
For in vitro diagnostic use only.
【Test principle】
This kit uses immunochromatography for detection. Colloidal gold was used as a marker to qualitatively detect SARS-CoV-2 novel coronavirus N protein antigen in human saliva samples.The specimen will move forward along the test card under capillary action. If the specimen contains a novel coronaviruses antigen, the antigen will bind to the colloidal gold-labeled novel coronavirus monoclonal antibody to form an immune complex. The immune complex will be membrane fixed will be novel coronavirus monoclonal antibody capture, form the fuchsia line, display will be novel coronavirus 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.
【Main components】
· Test card · Desiccant Bag · Instructions for use
【Storage conditions & period of validity】
1. Store at 2℃~30℃, and it is valid for 24 months.
2. After the aluminum foil bag is unsealed, the test card should be used as soon as possible within one hour.
【Specimen request】
1.For saliva specimens, rinse the mouth with water within 30 minutes before collecting the sample in order to ensure that enough cells are collected. Do not collect saliva samples immediately after rinsing the mouth. Saliva should come from deep oral secretions.
2. suffering from severe oral ulcers or bronchitis and other diseases that can affect saliva collection.
3. The samples should be used as soon as possible after collection and should not be stored at room temperature for a long time.
4. If the sample cannot be detected in time, it can be stored at 2℃ -8℃ for 48 hours. Long-term storage should be frozen at 20℃ to avoid repeated freezing and thawing. As soon as possible after collection, the samples should be processed with virus sampling solution or sample extract solution provided by this reagent. If immediate processing is not possible, the specimen should be immediately stored in a dry, disinfected and tightly sealed plastic tube, which can be stored at 2 ° C to 8 ° C for 8 hours and at − 70 ° C for a long time.
5. Different subject samples should avoid mutual contact contamination.
【Test methods】
1. Take out the test card from the aluminum foil bag and place it on a clean and flat table.
2. Remove the cover of the test card, wipe the oral cavity with the collection cotton on the top of the test card for 2~3 times.
3. Keep your head down and hold the collection cotton in your mouth (make sure the test card is perpendicular to the ground), wait 1-3 minutes until the saliva turns to light red in the observation window.
4. After the saliva turns to light red in the observation window, take out the test card from your mouth and cover it. Place the test card on a clean and flat table, and start timing at the same time.

Sample collection



Saliva collection cotton

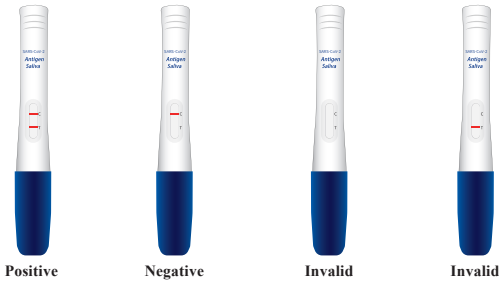
Remove the cover of the test card, wipe the oral cavity with the collection cotton on the top of the test card for 2~3 times.

Vertical ground

Keep your head down and hold the collection cotton in your mouth (make sure the test card is perpendicular to the ground), wait 1-3 minutes until the saliva turns to light red in the observation window

After the saliva turns to light red in the observation window,take out the test card from your mouth and cover it. Place the test card on a clean and flat table, and start timing at the same time.

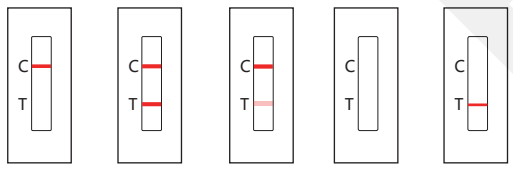
Test Results



Positive **Negative** **Invalid** **Invalid**

Read the result between 10-20 minutes. A strong positive result can be reported within 10 minutes, however, a negative result must be reported after 20 minutes, and the results after 30 minutes are no longer valid.

Notes on saliva collection
Don't eat, drink, smoke, chew gum or put on lipstick for 30 minute before the test.



Negative Positive Positive Invalid Invalid

【Interpretation of Test Results】
Negative result: if there is only a quality control line C, the detection line is colorless, indicating that novel coronavirus antigen has not been detected and the result is negative.
Positive result: if both the quality control line C and the detection line appear, novel coronavirus 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 , and the test shall be conducted again. Pay particular attention to whether the sample size is sufficient.

【Limitations of inspection methods】
1. This kit is for the detection of human saliva samples only. Results from other specimens may be erroneous.
2. The accuracy of the test depends on the process of collecting the sample, and improper sample collection, improper sample storage, or repeated freezing and thawing of the sample can affect the test results.
3. This product can only qualitatively detect novel coronavirus N protein antigen in human saliva samples and cannot accurately determine the content of antigen in samples. If you need to detect the specific content, please use the relevant professional instruments.
4. The detection results of this reagent are only for clinical reference and shall not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients shall be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment reactions.
5. Due to the limitation of antigen detection reagent methodology, for negative detection results, it is recommended to use nucleic acid detection or virus culture and identification methods for review and confirmation.
6. When the prevalence of the disease decreases, the positive predictive value decreases, so the interpretation of positive results in low-risk groups should be cautious.
7. This reagent is a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time, based on the doctor's diagnosis.
8. analysis of the possibility of false negative results:
   1) Unreasonable sample collection, transportation and treatment.
   2) There was no virus in the sample, or the virus content in the sample was very low, which was lower than the critical detection concentration of the reagent, and the low-concentration sample could not be detected. Viral genetic variants may lead to changes in antigenic determinants, resulting in false negative results.
   3) The optimal sample type and the optimal sampling time after infection (peak virus) are not verified, therefore, it is possible to avoid false negatives by collecting samples at multiple sites in multiple fractions from the same patient.
   4) The virus in the sample may have been inactivated. Although nucleic acid fragments may remain, viral antigens may have been destroyed and inactivated.
【Quality control 】
A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

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【Preformance】

1.Minimum detection limit:

The study determined the minimum detection concentration of SARS-CoV-2 by diluting heat-killed SARS-CoV-2 virus (stock concentration of 3.5×10^5 TCID$_{50}$ / mL) into negative specimens. Each concentration was diluted in triplicate. The detection limit of this assay was 3.5×10^2 TCID$_{50}$ / mL (Table 1).

Table 1 The limit of detection (LOD) study results

Concentration	Positive/Total	Positive rate
3.5×10^2 TCID$_{50}$ / mL	60/60	100%

2.Sensitivity,Specificity and Accuracy

A total of 150 postive samples(with Covid-19 symptoms within 0-7 days of onset of symptoms) and 220 negative samples（without a specific exposure risk in the SARS-CoV-2 ） were detected in this clinical trial（by RT-PCR）, and each of them was evaluated by the evaluation kit and contrast kit.

Saliva Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	143	0	143
	Negative	7	220	227
Total		150	220	370

The SARS-CoV-2 Antigen Detection Kit ((Saliva) showed 95.33% sensitivity and 100% specificity in saliva samples.
Clinical sensitivity (%) = [143/ (143+7)] ×100% = 95.33%，(95%CI 90.62%-98.10%)
Clinical specificity (%) = [220/ (0+220)] ×100% = 100%，(95% CI 98.34%-100%)
Total agreement rate (%)=[(143+220) / (143+7+0+220)] ×100%=98.11% (95% CI 96.14%-99.24%)

3. Hook effect

Testing of 3.5×10^5 TCID$_{50}$/ mL SARS-CoV-2 virus after heat inactivation resulted in no Hook effect for the assay.

4. Cross-reactivity

Cross-reactivity with the following organisms was investigated. Samples that were positive for the following organisms tested negative with this assay.
After heat inactivation of 3.5×10^3 TCID$_{50}$/mL SARS-CoV-2 virus, the following microorganisms (Table below) showed no cross reaction with the detection reagent at the following concentrations.

Table 3

Pathogens	Concentration	Pathogens	Concentration	Pathogens	Concentration
Respiratory syncytial virus Type A	5.5×10^7PFU/mL	Mycobacterium tuberculosis	1×10^5bacteria/mL	Streptococcus pneumoniae	4.2×10^6CFU/mL
Respiratory syncytial virus Type B	2.8×10^6TCID$_{50}$/mL	Mumps virus	1×10^6PFU/mL	Candida albicans	1×10^7CFU/mL
Novel influenza A H1N1 virus (2009)	1×10^6PFU/mL	Human coronavirus 229E	1×10^6PFU/mL	Bordetella pertussis	1×10^4bacteria/mL
Seasonal influenza A H1N1 virus	1×10^6PFU/mL	Human coronavirus OC43	1×10^6PFU/mL	Legionella pneumophila	1×10^5bacteria/mL
Influenza A H3N2 virus	1×10^6PFU/mL	Human coronavirus NL63	1×10^6PFU/mL	Staphylococcus aureus	3.2×10^5CFU/mL
Influenza A H5N1 virus	1×10^6PFU/mL	Human coronavirus HKU1	1×10^6PFU/mL	Staphylococcus epidermidis	2.1×10^5CFU/mL
Influenza B Yamagata	1×10^5PFU/mL	Parainfluenza virus 1	7.3×10^6PFU/mL	Candida albicans	1×10^7CFU/mL
Influenza B Victoria	1×10^6PFU/mL	Parainfluenza virus 2	1×10^6PFU/mL	Bordetella pertussis	1×10^4bacteria/mL
Rhinovirus	1×10^6PFU/mL	Parainfluenza virus 3	5.8×10^6PFU/mL	Mycoplasma pneumoniae	1.2×10^6CFU/mL
Adenovirus 3	5×10^7TCID$_{50}$/mL	Parainfluenza virus 4	2.6×10^6PFU/mL	Chlamydia pneumoniae	2.3×10^6IFU/mL
Adenovirus 7	2.8×10^6TCID$_{50}$/mL	Haemophilus influenzae	5.2×10^6CFU/mL	Pooled human mouthwash	N/A
EV-A71	1×10^6PFU/mL	Streptococcus pyogenes	3.6×10^6CFU/mL		

5. Interfering Substances

The following substances (Table below), which are naturally present in respiratory specimens or may be artificially introduced into the nasal cavity, nasopharynx, or saliva, were evaluated at the following concentrations when tested with the assay and found not to affect the performance of the test.

Table 4

Substance	Concentration
Human blood (EDTA anticoagulated)	20% (v/v)
Mucin	5 mg/mL
Oseltamivir phosphate	5 mg/mL
Ribavirin	5 mg/mL
Levofloxacin	5 mg/mL
Azithromycin	5 mg/mL
Meropenem	5 mg/mL
Tobramycin	2 mg/mL
Phenylephrine	20% (v/v)
Oxymetazoline	20% (v/v)
0.9% sodium chloride	20% (v/v)
A natural soothing ALKALOL	20% (v/v)
Beclomethasone	20% (v/v)
Hexadecadrol	20% (v/v)
Flunisolide	20% (v/v)
Triamcinolone	20% (v/v)
Budesonide	20% (v/v)
Mometasone	20% (v/v)
Fluticasone	20% (v/v)
Fluticasone propionate	20% (v/v)

【Precautions】

1. For professional in vitro diagnostic use only and not for home use. Do not use after expiration date.
2. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
3. The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.
4. Guard against moisture, do not open the aluminum platinum bag before it is ready for testing. Do not use the aluminum foil bag when it is damaged or the test card is damp.Aluminum foil bag desiccant, do not take orally.
5. Balance all reagents and specimens to room temperature (15～30 ℃) before use.
6. Do not replace the components in this kit with components in other kits.
7. Do not dilute the specimen for testing, otherwise you may get inaccurate results.
8. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
9. The test methods and results must be interpreted in strict accordance with this specification.
10. Negative results will occur with this kit if the novel coronavirus antigen titer in the specimen falls below the minimum detection limit for this kit.

【Bibliography】

[1] World Health Organization: Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance. 12 January, 2020.
[2] Chen, Yu, Lanjuan Li, et al. "SARS-CoV-2: virus dynamics and host response." The Lancet Infectious Diseases,2020,Vol. 20(5): 515-516.

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

Approval Date: May, 15th, 2020
Revision Date: Jan, 1st, 2021
Date of Issue: Jan, 26th, 2021

【Index of CE Symbols】

IVD	The product is used in vitro,please don't swallow it.		Please don't re-use it.		Validity
	Please read the instruction book carefully before using.		Warning, please refer to the instruction in the annex.		Manufacturer
4℃ 30℃	Temperature scope within which the product is reserved.	LOT	Batch number	EC REP	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	CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive IVDD 98/79/EC

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