English

SARS-CoV-2 Ag Rapid Test Kit

Package Insert

Version: 02 **Specimen:** Saliva

PRODUCT NAME

SARS-CoV-2 Ag Rapid Test Kit

PACKING

Type I (1 piece/bag, 1 piece/box)
Type II (1 piece/bag, 5 pieces/box)
Type III (1 piece/bag, 10 pieces/box)
Type IV (1 piece/bag, 25 pieces/box)
Type V (1 piece/bag, 50 pieces/box)

INTENDED USE

This product is intended for the qualitative detection of novel coronavirus, or COVID-19, in Saliva. It aids in the diagnosis of infection with the novel coronavirus.
It can be used as a supplementary test for COVID-19 diagnosis.

SUMMARY

The novel coronaviruses (SARS-CoV-2) belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible to infection. 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, particularly 3 to 7 days. The main symptoms include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are also found in some cases.

PRINCIPLE

The SARS-CoV-2 Ag Rapid Test Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein and spike protein from SARS-CoV-2 in Saliva samples. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-carbon conjugated with the monoclonal antibodies against the nucleocapsid protein and spike protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein and spike protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a dark line will always appear in the control line region (C), indicating that proper volume of sample has been added and membrane working has occurred.

COMPOSITION

1. Disposable test device

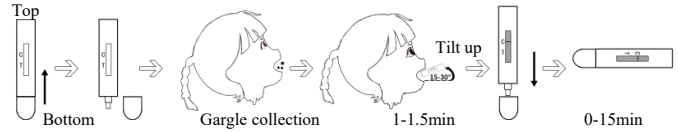
STORAGE AND STABILITY

1. Store as packaged in the hermetically-sealed bag at the temperature (2-30℃ or 38-86℉) and avoid direct sunshine. The kit is stable within the expiration date (2 years) printed on the labeling.
2. Once the sealed bag is opened, the test should be used within one hour. Prolonged exposure to hot and humid environments will cause product deterioration.
3. The lot number and the expiration date are printed on each sealed bag.

TEST PROCEDURE

Allow the test device and specimens to equilibrate to room temperature (15-30℃ or 59-86℉) prior to testing.

TEST ME THOD 1:



1. Cough deeply, gargle with 1 tablespoon (about 5~10mL) of water and hold the water in the mouth, make the noise of "Kruuua" from the throat to enrich and transfer saliva from the deep throat to the oral cavity for 10~20 seconds. Hold the water till the test finishes.
2. Pull out the cap of the test card and place the tampon at the bottom of the test card in your mouth, tilt the tip up at an angle of 15 to 30 degrees and keep it and let saliva fully wet the tampon, do not blow or inhale.
3. Wait 1-1.5 minutes for the liquid to climb to the top of the reading window. Remove the test card, close the lid, and place the test card flat on the desktop.
4. Read the result within 15 minutes. For a positive sample, it can be determined when the T line appears, and there is no need to wait for extra time.

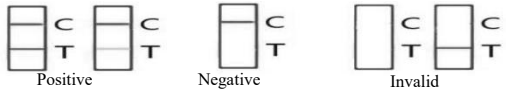
TEST ME THOD 2：Mouthwash detection

This method does not need to contain the test strip cotton bar in mouth, especially suitable for children. The operation steps are as follows:

1. Before brushing your teeth in the morning, shut up and cough 3 to 5 times, preferably if you can cough up sputum, because the viral load of the lower respiratory tract is higher;
2. Take about 5ml of mouthwash in your mouth, tilt your head slightly and rinse your throat, then rinse your mouth;
3. Spit mouthwash sputum or saliva into a small cup or lid and hand it to parents for operation;
4. Parents operate COVID-19 test kits;
5. Tear the aluminum foil bag containing the strip, take out the strip, and gently remove the lid (Note: do not pull out the cotton bar!) ;
6. Soak the absorbent cotton bar at the tip of the strip into the cup or lid containing the mouthwash sample. Hold the strip at an Angle of 100-300 degrees.
7. Pay attention to the water running board. When the water runs to line C or the whole observation window (the time can be long or short, generally 0.5-1.5min), take out the test strip and put it flat on the table;
8. The results can be read after 15 minutes and are valid within 1 hour. The results are invalid after 1 hour.

INTERPRETATION OF RESULTS (WITHIN 15 MINUTES)

Positive (+): Both of T and C lines appear within15minutes.
Negative (-): C line appears while no T line appears after 15 minutes.
Invalid: If the C line does not appear, indicating that the test result is invalid, and you should retest the specimen with another test devic



NOTES

1. SARS-CoV-2 Ag Rapid Test Kit is only applicable to saliva samples. Blood, serum, plasma, urine, and other samples may cause abnormal results. If any sample is tested positive, please see your local healthcare authority for further clinical diagnosis and reporting of results.
2. The key to the test is to collect the high-load virus in the throat and deep throat by gargle. The viral load of pure oral saliva is too low to be tested.
3. When holding the test strip, the top of the test strip should be tilted up at an angle of 10 to 30 degrees instead of downward.
4. Let the sliver be naturally moistened. It is forbidden to inhale from the sliver or blow into the sliver.
5. For positive judgment, it can be confirmed as soon as both T and C lines have appeared, typically 0-15 minutes after the reading window is completely wet. For negative judgment, please wait for 15 minutes after the sample has been added. The C line will appear alone while no T line will be present.
6. The test device is a disposable product and will contain biohazards after use. Please properly dispose of the test devices, specimens, and all collection materials after use.
7. The product must be used prior to the expiration date on product labeling.
8. If part of the test membrane containing the reagents is out of the test window, or more than 2 mm of filter paper or sample pad is exposed in the test window, do not use it because the test results will be invalid. Use a new test kit instead.

PERFORMANCE CHARACTERISTICS:

1. Clinical Performance

A clinical evaluation was carried out to confirm that the sensitivity and specificity of the SARS-CoV-2 Ag Rapid Test Kit for SARS-CoV-2, and the results of SARS-CoV-2 Ag Rapid Test Kit were compared with those of RT-PCR. The results are as follows summarized:

Saliva Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	453	0	453
	Negative	23	709	732
Total		476	709	1185

Clinical sensitivity (%) = [453/ (453+ 23)] ×100% = 95.2% (92.9%~96.8%);
Clinical specificity (%) = [709/ (0+ 709)] ×100% = 100% (99.5%~100%);
Total agreement rate (%) = [(453 +709) / (453+ 23+ 0+ 709)] ×100% = 98.1% (99.0%~100%);

2. Limit of Detection (LoD)

SARS-COV-2 nucleocapsid protein and spiker protein expressed in vitro were used for Limit of Detection (LoD) tests. The LoD of the SARS-CoV-2 Ag Rapid Test Kit is 5 pg/mL SARS-COV-2 nucleocapsid protein. The LoD of the SARS-CoV-2 Ag Rapid Test Kit is 20 pg/mL SARS-COV-2 spiker protein. The LoD of the SARS-CoV-2 Ag Rapid Test Kit is 1.8×10^2 $TCID_{50}$/mL SARS-COV-2 strain.

N-protein	Saliva	S-protein	Saliva
40 pg/mL	50/50 (100%)	160 pg/mL	50/50 (100%)
20 pg/mL	50/50 (100%)	80 pg/mL	50/50 (100%)
10 pg/mL	50/50 (100%)	40 pg/mL	50/50 (100%)
5 pg/mL	49/50 (98%)	20 pg/mL	49/50 (98%)
2.5 pg/mL	15/50 (30%)	10 pg/mL	13/50 (26%)
0 pg/mL	0/50 (0%)	0 pg/mL	0/50 (0%)

Dilution	Concentration TCID50/mL	saliva Sample
1:10	3.5×10^4	50/50 (100%)
1:100	3.5×10^3	50/50 (100%)
1:200	1.6×10^3	50/50 (100%)
1:500	6.8×10^2	50/50 (100%)
1:1000	3.5×10^2	50/50 (100%)
1:2000	1.8×10^2	48/50 (96%)
1:4000	0.8×10^2	36/50 (72%)

3. Recognition performance for mutant viruses:

This study tested the reliability of the SARS-CoV-2 Ag Rapid Test Kit by spiking different kinds of nucleocaspid proteins or spiker proteins of SARS-CoV-2 mutant virus (10×LoD) into the tested samples.

	N-protein of mutant virus	S-protein of mutant virus
Alpha (B.1.1.7)	50/50 (100%)	50/50 (100%)
Beta (B.1.351)	50/50 (100%)	50/50 (100%)
Gamma (P.1)	50/50 (100%)	50/50 (100%)
Delta (B.1.617.2)	50/50 (100%)	50/50 (100%)
Eta (B.1.525)	50/50 (100%)	50/50 (100%)
Lota (B.1.526)	50/50 (100%)	50/50 (100%)
Kappa (B.1.617.1)	50/50 (100%)	50/50 (100%)
Lambda (C.37)	50/50 (100%)	50/50 (100%)
Mu (B.1.621)	50/50 (100%)	50/50 (100%)
C.1.2	50/50 (100%)	50/50 (100%)
B.1.618	50/50 (100%)	50/50 (100%)
P.2	50/50 (100%)	50/50 (100%)
D614G	50/50 (100%)	50/50 (100%)
501Y.V2	50/50 (100%)	50/50 (100%)
Omicron（B.1.1.529）	50/50 (100%)	50/50 (100%)

4. Cross-reactivity:

The cross-reactivity with the following organisms and viruses was examined. The following substances will not produce false positive or false negative reactions when tested with the SARS-CoV-2 Ag Rapid Test Kit for the SARS-CoV-2.

Organism	Concentration ($TCID_{50}$/mL)	Organism	Concentration ($TCID_{50}$/mL)
HKU1	1.5×10^6	Enterovirus D	4×10^5
OC43	1.5×10^6	Epstein-Barr virus	2.5×10^5
NL63	1.5×10^6	Measles virus	3×10^5
229E	1.5×10^6	Human cytomegalovirus	3×10^5
MERS	1.5×10^6	Rotavirus	5×10^5
Influenza A H1N1	3×10^5	Norovirus	5×10^5
Seasonal Influenza H1N1	2×10^5	Mumps virus	5×10^5
Influenza A H3N2	3×10^5	Rhinovirus C	2.5×10^5
Influenza A H5N1	3×10^5	Adenovirus type 1	5×10^5
Influenza A H7N9	3×10^5	Adenovirus type 2	5×10^5
Influenza B	5×10^5	Adenovirus type 3	5×10^5
Syncytial virus	4×10^5	Adenovirus type 4	3.5×10^5
Rhinovirus A	2.5×10^5	Adenovirus 5	5×10^5
Rhinovirus B	2.5×10^5	Adenovirus type 7	3.5×10^5
Adenovirus 55	4×10^5	Enterovirus B	4×10^5
Enterovirus A	4×10^5	Enterovirus C	4×10^5
Varicella-zoster virus	5×10^5	Chlamydia pneumoniae	4.5×10^4 cells/mL
Human Metapneumovirus (hMPV)	4×10^5	Legionella pneumophila	6×10^4 cells/mL
Parainfluenza virus 1	4×10^5	Staphylococcus aureus	6×10^4 cells/mL
Parainfluenza virus 2	2.5×10^5	Streptococcus pneumoniae	5×10^4 cells/mL
Parainfluenza virus 3	3×10^5	Streptococcus pyogenes	5×10^4 cells/mL
Parainfluenza virus 4	3×10^5	Candida albicans	5×10^4 cells/mL
Respiratory syncytial virus	3.5×10^5	Pooled human sampling site wash	4.5×10^4 cells/mL
Haemophilus influenzae	5×10^5	Bordetella pertussis	4.5×10^4 cells/mL
Mycoplasma pneumoniae	6×10^4 cells/mL		

5. Endogenous/exogenous material interference test

The following substances, which occur naturally in breath samples or which can be artificially introduced into the airways, were evaluated as listed below. The SARS-CoV-2 Ag Rapid Test Kit does not report false positive or false negative.

Substance	Substance	Substance	Substance
Purified Mucin	Total IgM	Ritonavir	Oxymetazoline
Bilirubin	Hematocrit	Abidol	Sodium chloride
Blood lipids	Meropenem	Levofloxacin	Beclomethasone
Hemoglobin	alpha-interferon	Azithromycin	Dexamethasone
Rheumatoid factor	Zanamivir	Ceftriaxone	Flunisolone
Antinuclear antibody	Ribavirin	Fluticasone	Triamcinolone
Antimitochondrial antibody	Oseltamivir	Tobramycin	Budesonide
HAMA	Paramivir	Histamine hydrochloride	Momisson
Total IgG	Lopinavir	Benfurin	

6. Hook effect

The hook effect refers to the false-negative phenomenon caused by the incorrect ratio of antigen to antibody. For SARS-CoV-2 Ag Rapid Test Kit, even if the concentration of SARS-COV-2 nucleocapsid protein or spiker protein reaches 200μg/mL, the SARS-CoV-2 Ag Rapid Test Kit still has no hook effect.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30℃	LOT	Lot Number		Date of Manufacture

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