JUCHENGMEDICAL

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SARS-CoV-2 Ag Rapid Test Kit
Package Insert

Cat: HY03
Version: 03

Specimens: Saliva
Effective Date: 2021-06

For professional and in vitro diagnostic use only.

【PRODUCT NAME】

SARS-CoV-2 Ag Rapid Test Kit

【PACKING 】

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

【INTENDED USE】

This product is suitable for the qualitative detection of novel coronavirus, or COVID-19, in Saliva. It aids in the diagnosis of infection with novel coronavirus.

【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 Spiker protein from SARS-CoV-2 in Sputum/oropharyngeal 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 colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2 and colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein and S 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 red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

【COMPOSITION】

1.Disposable test dervice.

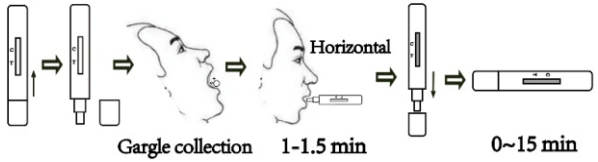
【STORAGE AND STABILITY】

1.Store as packaged in the hermetically-sealed bag at the temperature (2-30□or 38-86°F) and avoid direct sunshine. The kit is stable within the expiration date 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】

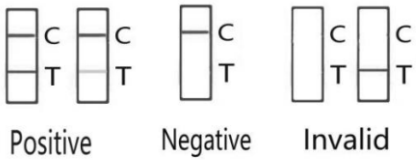
Allow the test device and specimens to equilibrate to room temperature (15-30°C or 59-86°F) prior to testing.

TEST METHOD 1 :



1.Gargle with 5~10 mL water for about 10 seconds raise head and cough deeply and collect sputum/oropharyngeal saliva or mucus which from the deep throat at the same time.
2.Put the tampon of the test card into the mouth, gently bite the end of the plastic card housing, and keep the horizontal state of the test card, and wait for 1-3 minutes until the wet liquid reaches the top of the observation window,
3.When the wet liquid arrives at the top of the observation window, remove the test card and close the cover. Place it flat on the desktop and wait for 0-15min.

【INTERPRETATION OF RESULTS (WITHIN 15 MINUTES)】



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

【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 tests positive, please see your local healthcare authority for further clinical diagnosis and reporting of results.
2.Make sure that the tampon is fully moistened. And wet liquid will arrive at the top of the observation window in 1-1.5 minutes.
3.Keep the horizontal state of the test card during testing.
4.Positive results can be judged immediately if C ling and T line appear,and negative results need to spend full 15minutes.
5.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.
6.Must use prior to the expiration date on product labeling.
7.If part of the test membrane containing the reagents is out of the test window, or more than 2 mm of filter paper or latex 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, compare results and RT-PCR. The results are as follows summarized:

(sputum/oropharyngeal saliva) Sample		RT-PCR		Total
		Positive	Negative	
Test reagent	Positive	98	0	98
	Negative	9	105	114
Total		107	105	212

(Sputum/oropharyngeal saliva) samples: The SARS-CoV-2 Ag Rapid Test Kit showed 91.6% sensitivity and 100% specificity in (sputum/oropharyngeal saliva) samples.
Clinical sensitivity (%) = [98/ (98+ 9)] ×100% =91.6%, and the 95% confidence interval is 90.01%-97.53%
Clinical specificity (%) = [105/ (0+ 105)] ×100% = 100%, and the 95% confidence interval is 97.61%-100%
Total agreement rate (%) = [(98 +105) / (98+ 9+ 0+ 105)] ×100% = 95.8%

2. Limit of Detection (LoD)
SARS-COV-2 nucleocapsid protein expressed in vitro and National Standard Reference sample of SARS-CoV-2 were used for Limit of Detection (LoD) tests. The LOD of the SARS-CoV-2 Ag Rapid Test Kit is 10 pg/mL SARS-COV-2 nucleocapsid protein. The LOD of the SARS-CoV-2 Ag Rapid Test Kit is 1×10^3TCID50/mL SARS-COV-2 .

N-protein	Saliva	National Standard Reference sample	Saliva
500 pg/mL	30/30 (100%)	1×10^3TCID50/mL	30/30 (100%)
100 pg/mL	30/30 (100%)	1×10^2TCID50/mL	30/30 (100%)
50 pg/mL	30/30 (100%)	1×10^1TCID50/mL	30/30 (100%)
10 pg/mL	28/30 (93.3%)	1×10^0TCID50/mL	29/30 (96.7%)
0.5pg/mL	6/30 (20%)	1×10^{-1}TCID50/mL	6/30 (20%)
0 pg/mL	0/30 (0%)	0 TCID50/mL	0/30 (0%)

3. Recognition performance for mutant viruses:
Spiked different kind of National Standard Reference sample of SARS-CoV-2 mutant virus (1×10^3TCID50/mL) to saliva sample. According to the test results, The detection performance of SARS-CoV-2 Ag Rapid Test Kit is suitable for a variety of SARS-CoV-2 mutant virus strains

	Saliva		Saliva
B.1.618	50/50(100%)	B.1.1.7	50/50(100%)
B.1.617.1	50/50(100%)	P.1	50/50(100%)
B.1.617.2	50/50(100%)	D614G	50/50(100%)
B.1.1.351	50/50(100%)	501Y.V2	50/50(100%)

4. Cross-reactivity:
The cross-reactivity with the following organism and virus 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 (TCID50/mL)	Organism	Concentration (TCID50/mL)
HKU1	1.5×10^6	EnterovirusD	4×10^5
Oc43	1.5×10^6	Epstein-Barr virus	2.5×10^5
NI63	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	4.5×10^5 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	5×10^5 cells/mL
Respiratory syncytial virus	3.5×10^5	Pooled human sampling site wash	4.5×10^4cells/mL
Haemophilus influenzae	5×10^5	Bordetella pertussis	4.5×10^4cells/mL
Mycoplasma pneumoniae	6×10^4cells/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	MucinTotal Ig	Mritonavir	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 reaches 200μg/mL, the SARS-CoV-2 Ag Rapid Test Kit still has no hook effect.

7.INDEX DER SYMBOLE

	Gebrachsanweisung beachten	Σ	Tests pro Kit	EC REP	Autorisierter Vertreter
IVD	Nur für In-vitro-Diagnostik		Verwendbar bis		Nicht wiederverwendbar
2° 30°	Lagerung bei 2-30 °C	LOT	Chargennummer	REF	Katalog-Nummer

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