SARS-CoV-2 Ag Rapid Test Kit

Package Insert

Cat: HY-05
Version: 03

Specimens: Saliva
Effective Date: 2021-06

For in vitro diagnostic use only.

PRODUCT NAME
SARS-CoV-2 Ag Rapid Test Kit

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.

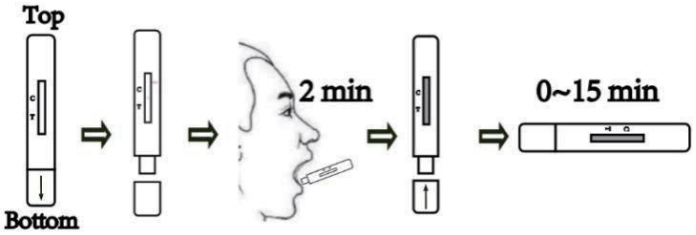
PRINCIPLE
The SARS-CoV-2 Ag Rapid Test Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in Saliva samples. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid 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
2. Disposable paper cup

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 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.

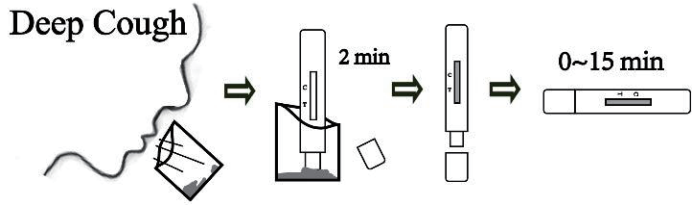
TEST PROCEDURE
Allow the test device and specimens to equilibrate to room temperature (15-30℃ or 59-86℉) prior to testing.

TEST METHOD 1 :



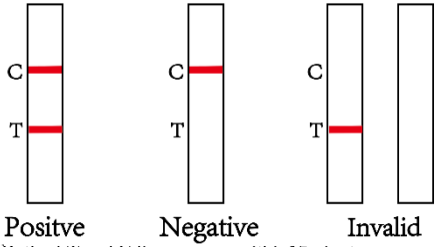
1. Rinse and spit with water to clear oral bacteria.
2. Cough deeply, Make the noise of "Kruuua" from the throat to enrich and transfer saliva from the deep throat to the oral cavity.
3. Pull out the cap of the test card and place the tampon which at the end of the test card under your tongue, let saliva fully wets the tampon.
4. Wait 2 minutes for the wet 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.
5. 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 METHOD 2:



1. Rinse and spit with water to clear oral bacteria.
2. Cough deeply, Make the noise of "Kruuua" from the throat to enrich and transfer saliva from the deep throat spit to the paper cup.
3. Pull out the cap of the test card and place the tampon which at the end of the test card in the paper cup, let saliva fully wets the tampon.
4. Wait 2 minutes for the wet 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.
5. 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.

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 contained under the tongue and is fully moistened. You can put the top of the test strip down to make the saliva faster accelerated by gravity into the detection window. For positive judgment, it can be confirmed as soon as both T and C line has 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.
3. 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.
4. Must use prior to the expiration date on product labeling.
5. 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:

Saliva Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	113	0	113
	Negative	7	120	127
Total		120	120	240

Clinical sensitivity (%) = [113/ (113+ 7)] ×100% = 94.2%，and the 95% confidence interval is 92.37%-98.73%;
Clinical specificity (%) = [120/ (0+ 120)] ×100% = 100%，and the 95% confidence interval is 97.96%-100%;
Total agreement rate (%) = [(113 +120) / (113+ 7+ 0+ 120)] ×100% = 97.1%

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 0.5 pg/mL SARS-COV-2 nucleocapsid protein. The LOD of the SARS-CoV-2 Ag Rapid Test Kit is 1×10^4TCID$_{50}$/mL SARS-COV-2 .

N-protein	Saliva	National Standard Reference sample	Saliva
10 pg/mL	50/50 (100%)	1×10^2TCID$_{50}$/mL	50/50 (100%)
5 pg/mL	50/50 (100%)	1×10^3TCID$_{50}$/mL	50/50 (100%)
1 pg/mL	50/50 (100%)	1×10^4TCID$_{50}$/mL	49/50 (98%)
0.5 pg/mL	49/50 (98%)	1×10^5TCID$_{50}$/mL	13/50 (26%)
0.1 pg/mL	13/50 (26%)	1×10^6TCID$_{50}$/mL	0/50 (0%)
0.05 pg/mL	0/50 (0%)	0 TCID$_{50}$/mL	0/50 (0%)
0 pg/mL	0/50 (0%)		

3. Recognition performance for mutant viruses:

Spike a healthy saliva sample into saline water, respectively. Prepare the supernatant for subsequent use. Spiked different kind of National Standard Reference sample of SARS-CoV-2 mutant virus ($1\times10^3 TCID_{50}$/mL). 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 ($TCID_{50}$/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 reaches 200μg/mL, the SARS-CoV-2 Ag Rapid Test Kit still has no hook effect.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
	Store between 2-30°C	LOT	Batch Number	REF	Catalogue number
	Manufacturer		Do not use if package is damaged		Manufacture date

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