IVD CE

COVID-19 Ag Rapid Saliva Test Device

Cat#: CO-07

For professional *in vitro* diagnostic use only.

Intended Use

COVID-19 Ag Rapid Saliva Test Device is a rapid chromatographic immunoassay for the qualitative detection of N antigen from SARS-CoV-2 present in human saliva within the first 7 days of symptom onset. This test is for professional used only, as an aid to early diagnosis of SARS-CoV-2 infection in patient.
The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

Summary

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or "SARS-CoV-2 (COVID-19)" named by the World Health Organization can cause pneumonia epidemic.
The detection results of this kit are for clinical reference only. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

Principle

The COVID-19 Ag Rapid Saliva Test Device uses double antibody sandwich immunoassay. The NC membrane pre-immobilized with monoclonal antibodies against SARS-CoV-2 antigen and anti-mouse polyclonal antibodies, and the colloidal-gold conjugated with monoclonal antibodies specific to SARS-CoV-2 antigen.
If SARS-CoV-2 antigen present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the antigen will be caught by the specific anti- SARS-CoV-2 monoclonal coated on the T region. Results appear in 10 to 20 minutes in the form of a red line that develops on the strip.
Whether the sample contains the SARS-CoV-2 antigen or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

Kit Content

1) Test device (individually packed in a foil pouch with desiccant).
2) Instruction for use.

Materials required but not provided

Timer

Precautions

• For *in vitro* diagnostic use only.
• Do not re-use the test device.
• Do not use after the expiration date.
• Do not use the test kit if the pouch is damaged or the seal is broken.
• Perform test at room temperature 15 to 30 ℃.
•Wear gloves when hanging the samples, avoid touching the reagent membrane and sample window.
• All samples and used accessories should be treated as infectious and discarded according to local regulations.
• Avoid using blood samples.

Storage and Stability

Store the COVID-19 Ag Rapid Saliva Test Device at 2-30 ℃. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

Test Procedure

The COVID-19 Ag Rapid Saliva Test Device is designed for one-step test for COVID-19 antigen in human saliva..
Allow the test device to reach room temperature 15 - 30 ℃, and instruct the user not to eat, drink, smoke or chew tobacco products for at least 10 minutes prior to use the test.

1) Remove the test device from the sealed pouch and use the device as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2) Cough deeply twice before collecting the samples.
3) Pull the blue cap off gently by holding the sides to expose the collection pad.
4) Hold the top portion of the device and place the collection pad into the mouth.
5) Rub the collection pad against the cheek and tongue gently in a circular motion about 10 times. And then place the collection pad in the mouth for about 1~2 minutes until the C line show up in the C region.
6) Remove the device from mouth as soon as the C line appears at the C rigion.
7) Place the cap onto the device, lay it on a flat surface.
8) Read results at 10-15minutes after removing device from mouth. Do not read results after 20 minutes.

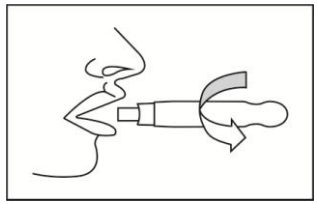


Fig. A Gently rub the collection pad against each cheek several times.

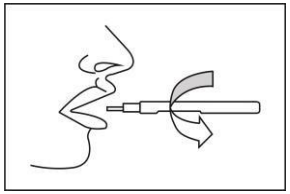


Fig B. Gently rub the collection pad on top of the tongue.

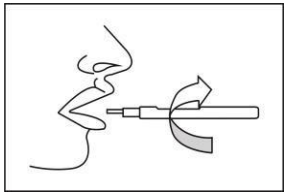
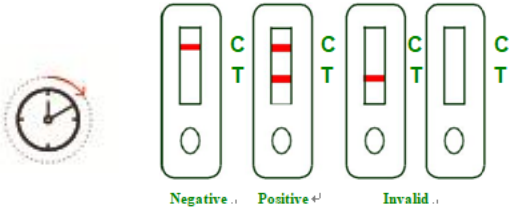


Fig C. Place the collection pad underneath the tongue.

Interpretation of Results

NEGATIVE:
Only one red band appears in the control region (C), and no band in the test region (T). The negative result indicates that there are no Novel coronavirus antigen in the sample or the number of viral particles is below the detectable range.
POSITIVE:
Two red bands appear. One red band appears in the control region (C), and one red band in the test region (T).
The shade of color may vary，but it should be considered positive whenever there is even a faint band.
INVALID:
No red band appears in the control region (C). The test is invalid even if there is a band on test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device.



Do not interpret the result after 20 minutes.

Limitations

IVD CE

• The COVID-19 Ag Rapid Saliva Test Device is an initial screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.
• The COVID-19 Ag Rapid Saliva Test Device detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
• A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
• Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
• Positive test results do not rule out co-infections with other pathogens.
• Negative test results are not intended to rule in other coronavirus infection except the SARS-CoV-2.
• Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children list.
• A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-Cov-2 infection, and should be confirmed by viral culture or a molecular assay or ELISA.

Performance Characteristics

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by COVID -19 Ag Rapid Saliva Test Device and PCR. The results were summarized below:

Table 1: COVID Ag Rapid Saliva Test Device vs. PCR

		COVID Ag Rapid Saliva Test Device		Total Result
		+	-	
PCR	+	129	6	135
	-	0	200	200
Total Results		129	206	335

Relative sensitivity: 129/135= 95.6% (95%CI 93.79%~98.66%)
Relative specificity: 200/200 >99% (95%CI 97.12%~100%)
Overall agreement: (129+200)/(129+0+6+200)×100%=98.21% (95%CI 96.55%~99.36%)
CI: Confidence Interval

Cross Reaction:

The COVID -19 Ag Rapid Saliva Test Device was evaluated with a total of 47 other viruses and bacteria. The results show that the COVID-19 Ag Rapid Saliva Test Device has no cross-reactivity with other viruses or microorganisms.

Table 2: Cross-reactivity results

Virus/Bacteria/Parasite	Strain	Concentration	Results
MERS-coronavirus	N/A	36 ug/mL	No Cross-Reactivity
Adenovirus	Type 1	1.5E+05TCID50/mL	No Cross-Reactivity
	Type 3	7.5E+05TCID50/mL	No Cross-Reactivity
	Type 5	4.5E+05TCID50/mL	No Cross-Reactivity
	Type 7	1.0E+05TCID50/mL	No Cross-Reactivity
	Type 8	1.0E+05TCID50/mL	No Cross-Reactivity
	Type 11	2.5E+05TCID50/mL	No Cross-Reactivity
	Type 18	2.5E+05TCID50/mL	No Cross-Reactivity
	Type 23	6.0E+05TCID50/mL	No Cross-Reactivity
	Type 55	1.5E+05TCID50/mL	No Cross-Reactivity
Influenza A	H1N1 Denver	3.0E+07TCID50/mL	No Cross-Reactivity
	H1N1 WS/33	2.0E+07TCID50/mL	No Cross-Reactivity
	H1N1 A/Mal/302/54	1.5E+07TCID50/mL	No Cross-Reactivity
	H1N1 New Caledonia	7.6E+07TCID50/mL	No Cross-Reactivity
	H3N2A/Hong Kong/8/68	4.6E+07TCID50/mL	No Cross-Reactivity
Influenza B	Nevada/03/2011	1.5E+07TCID50/mL	No Cross-Reactivity
	B/Lee/40	8.5E+07TCID50/mL	No Cross-Reactivity
	B/Taiwan/2/62	4.0E+07TCID50/mL	No Cross-Reactivity
Respiratory syncytial virus	N/A	2.5E+05TCID50/mL	No Cross-Reactivity
Legionella pneumophila	Bloomington-2	1×10^5 PFU/mL	No Cross-Reactivity
	Los Angeles-1	1×10^5 PFU/mL	No Cross-Reactivity
	82A3105	1×10^5 PFU/mL	No Cross-Reactivity
Mycobacterium tuberculosis	K	1×10^5 PFU/mL	No Cross-Reactivity
	Erdman	1×10^5 PFU/mL	No Cross-Reactivity
	HN878	1×10^5 PFU/mL	No Cross-Reactivity
	CDC1551	1×10^5 PFU/mL	No Cross-Reactivity
	H37Rv	1×10^5 PFU/mL	No Cross-Reactivity
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	1×10^5 PFU/mL	No Cross-Reactivity
	178 [Poland 23F-16]	1×10^5 PFU/mL	No Cross-Reactivity
	262 [CIP 104340]	1×10^5 PFU/mL	No Cross-Reactivity
	Slovakia 14-10 [29055]	1×10^5 PFU/mL	No Cross-Reactivity
Streptococcus pyrogens	Typing strain T1[NCIB 11841, SF 130]	1×10^5 PFU/mL	No Cross-Reactivity
Mycoplasma pneumoniae	Mutant 22	1×10^5 PFU/mL	No Cross-Reactivity
	FH strain of E aton Agent [NCTC10119]	1×10^5 PFU/mL	No Cross-Reactivity
	36M129-B7	1×10^5 PFU/mL	No Cross-Reactivity
Coronavirus	229E	1.5E+05TCID50/mL	No Cross-Reactivity
	OC43	1.5E+05TCID50/mL	No Cross-Reactivity
	NL63	1.5E+05TCID50/mL	No Cross-Reactivity
	HKU1	1.5E+05TCID50/mL	No Cross-Reactivity
Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002	1.5E+05TCID50/mL	No Cross-Reactivity
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	1.5E+05TCID50/mL	No Cross-Reactivity
Parainfluenza virus	Type 1	1.5E+05TCID50/mL	No Cross-Reactivity
	Type 2	1.5E+05TCID50/mL	No Cross-Reactivity
	Type 3	1.5E+05TCID50/mL	No Cross-Reactivity
	Type 4A	1.5E+05TCID50/mL	No Cross-Reactivity
RhinoVIRUS A16	N/A	1.5E+05TCID50/mL	No Cross-Reactivity
SARS-CoV-2	C-TAN-nCOV wuhan strain 01	1.5E+05TCID50/mL	No Cross-Reactivity

Microbial Interference:

Microbial interference study was performed to evaluate microbial interference effect, using samples spiked at 3×LoD SARS-CoV-2 concentration and a high interferent level.

Table 3: Microbial interference Results

No.	Microorganism	Concentration	Results

IVD CE

1	Streptococcus hemolyticus	1×10^5 cfu/ml	No Interference
2	Pseudomonas aeruginosa	1×10^5 cfu/ml	No Interference
3	Staphylococcus aureus	1×10^5 cfu/ml	No Interference
4	Escherichia coli	1×10^5 cfu/ml	No Interference
5	Candida albicans	1×10^5 cfu/ml	No Interference
6	Aspergillus niger	1×10^5 cfu/ml	No Interference

The results show that microorganism listed above has no microbial interference on the negative and positive test results, and these substances do not cross-react with COVID-19 Antigen Rapid Saliva Test Device.

Endogenous Interference:

The COVID -19 Ag Rapid Saliva Test Device was evaluated with a total of 13 endogenous interference substances.

Table 4: Endogenous Interference

Substance	Concentration	Results
Whole Blood	4%	No Interference
Mucin	0.5%	No Interference
Benzocaine	1.5 mg/mL	No Interference
NeilMed	5% v/v	No Interference
CVS Nasal Drops (Phenylephrine)	15% v/v	No Interference
Oxymetazoline)	15% v/v	No Interference
CVS Nasal Spray (Cromolyn)	15% v/v	No Interference
Zicam	5% v/v	No Interference
Sore Throat Phenol Spray	15% v/v	No Interference
Tobramycin	4 μg/mL	No Interference
Mupirocin	10 mg/mL	No Interference
Fluticasone Propionate	5% v/v	No Interference
Tamiflu	5 mg/mL	No Interference

The results show that endogenous interference substances listed in above table has no inference effect on the negative and positive test results, and these substances do not cross-react with COVID-19 Antigen Rapid Saliva Test Device.

Food/beverage Interference:

Food/beverage interference study was performed to evaluate the potential interference of food/beverage in saliva samples on the COVID-19 Antigen Rapid Saliva Test Device.

Table 5: Food/beverage interference Results

Substance	Concentration	Results
Mouth Wash	1%	No Interference
Orange Juice	1%	No Interference
Alcohol	1%	No Interference
MSG	1%	No Interference
Salt	1%	No Interference
Tooth Paste	1%	No Interference
Gum	1%	No Interference
Cough Syrup	1%	No Interference
Sugar	1%	No Interference
Tea	1%	No Interference
Food Color: red	1%	No Interference
Food Color: blue	1%	No Interference
Food Color: green	1%	No Interference
Cranberry Juice	1%	No Interference
Carbonated Cola	1%	No Interference
Baking Soda	1%	No Interference
Cigarette	1%	No Interference

The results show that 1% substance listed in above Table has no inference effect on the negative and positive test results, and these substances have no interference on COVID-19 Antigen Rapid Saliva Test Device.

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Symbols

Symbol	Meaning
	Consult instruction for use
	In-Vitro Diagnostic Medical Device
	Manufacturer
	Batch code
	Caution, consult accompanying documents
	Keep away from sunlight
	Do not reuse
	Temperature Limitation
	Use by date
	Production Date
	Contains sufficient for <n>test
EC REP	Authorized representative in the European Community
CE	Meet the requirements of EC Directive 98/79/EC

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