IVD CE

COVID-19 Ag Rapid Test Device

Cat# CO-05

For professional *in vitro* diagnostic use only.

Intended Use

COVID-19 Ag Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of N antigen to SARS-CoV-2 present in human nasal swabs. 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 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.)
2). Extraction tube
3). Extraction buffer
4). Sterile swab
5). Instruction for use

Materials Required but not Provided

1. Timer 2. Transfer pipette

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°C.
•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 Test Device at 2-30°C. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

Specimen Collection and Precaution

1. Specimen Collection:

Proper specimen collection, storage, and transport are critical to the performance of this test.

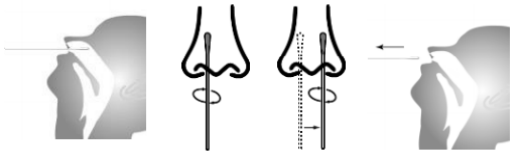
Specimens should be tested as soon as possible after collection. The training in specimen collection is highly recommended because of the importance of specimen quality. For optimal test performance, use the swabs supplied in the kit.

1) Carefully insert the swab into one nostril of the patient. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril.

2) Roll the swab 3-4 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Leave the swab in the nostril for several seconds.

3) Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

4). Withdraw the swab from the nasal cavity.



2. Specimen Preparation:

1) Take out 1 bottle of extraction buffer, break off the bottle cap, add all extraction buffer (about 0.3 ml) into the extraction tube.

2) Place the swab with specimen into the extraction tube. Roll the swab three to five (3-5) times. Leave the swab in the extraction buffer for 1 minute.

3) Pinch the extraction tube with fingers and remove the solution from the swab as much as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol sample is collected from both nasal cavities.

4) Install the nozzle cap onto the sample extraction tube tightly. Use extraction solution as test specimen.

Test Procedure

Allow the test, the specimen and the extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

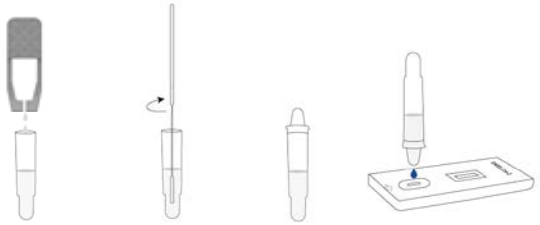
1) Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

2) Put the test device on a clean and level surface.

3) Shake the swab specimen in the collection tube to well mix.

4) Transfer 3 drops (~75µl) of the sample from the nozzle to the sample well of the test device and make sure a colored liquid appearing in the detection window in 30 seconds.

5) Start the timer. Read the result at 15~20 minutes. Do not interpret the result after 20 minutes.



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 particles 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.

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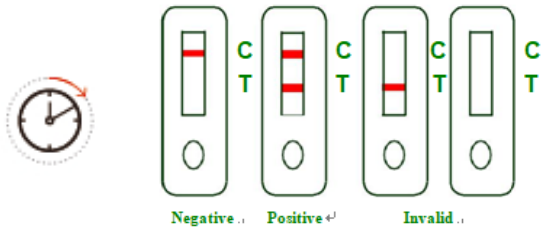
At 15~20 minutes



Do not interpret the result after 20 minutes.

Limitations

• The COVID-19 Ag Rapid 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 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 Test Device and PCR. The results were summarized below:

Table 1: COVID Ag Rapid Test Device vs. PCR

		COVID Ag Rapid Test Device		Total Result
		+	-	
PCR	+	126	7	133
	-	0	200	200
Total Results		126	207	333

Relative sensitivity: 126/133= 94.74% (95%CI 89.53%~97.43%)
Relative specificity: 200/200 >99% (95%CI 98.12%~100%)
Overall agreement: (126+200)/(126+0+7+200)*100%=97.90% (95%CI 95.73%~98.98%)
CI: Confidence Interval

Cross Reaction

The COVID -19 Ag Rapid Test Device was evaluated with a total of 47 other viruses and bacteria. The results show that the COVID-19 Ag Rapid 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
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 Test Device.

Endogenous Interference:

The COVID -19 Ag Rapid 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 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
	Authorized representative in the European Community
	Meet the requirements of EC Directive 98/79/EC