CE 1434 IVD

Covid-19 Antigen Rapid Test Kit(Colloidal Gold)
Instructions for Use(Anterior Nasal Swab)

For Self-testing

【INTENDED USE】

This test kit is used for rapid in vitro qualitative detection of SARS-CoV-2 antigens in human anterior nasal swab from individuals suspected of COVID-19 within the first 7 days of symptom onset. This test kit is for self-testing by lay person in a non-laboratory setting.

The test results of this test kit are for preliminary screening and clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information and further clinical data.

【TEST PRINCIPLE】

This kit uses immunochromatography for qualitative detection of SARS-CoV-2 nucleocapsid protein antigen present in anterior nasal swab specimen. The specimen will move forward along the test card under capillary action. If the specimen contains a SARS-CoV-2 antigen, the antigen will bind to the colloidal gold-labeled SARS-CoV-2 monoclonal antibody. The immune complex will be captured by SARS-CoV-2 monoclonal antibodies pre-coated on membrane strip, forming the fuchsia line, and this suggests the result is positive; if the line does not show color, it suggests the result is negative. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a test line.

【MATERIALS PROVIDED】

Components	Specification		
	1 Test/Kit	5 Tests/Kit	25 Tests/Kit
	CG01Ag-01N-ST	CG01Ag-05N-ST	CG01Ag-25N-ST
Anterior nasal swab	1	5	25
Extraction tube with extraction solution	1	5	25
Test card	1	5	25
Instructions for use	1	1	1
Tube rack	1 (packaging)	1	1

【PERFORMANCE CHARACTERISTICS】

Clinical performance

Method		PCR Comparator (nasopharyngeal swab specimen)		Total
	Results	Positive	Negative	
COVID-19 Antigen Rapid Test Kit(Colloidal Gold) (anterior nasal specimen)	Positive	110	1	104
	Negative	12	449	461
	Total	122	450	572

Sensitivity(true positive rate): 90.16% (95% CI, 83.59% ~94.28%)
Specificity(true negative rate): 99.78% (95% CI, 98.75% ~99.96%)
Accuracy(true positive and negative rate): 97.73% (95% CI, 96.15% ~98.67%)

Limit of Detection: 5×10^2 $TCID_{50}$/mL

【CROSS-REACTIVITY】

To evaluate the cross reactivity, the following panel of common organisms were tested with COVID-19 Antigen Rapid Test Kit(Colloidal Gold). Each of samples was tested in triplicate and no cross-reactivity was found.

Potential Cross-Reactant	Test Concentration	Potential Cross-Reactant	Test Concentration
Adenovirus	1.0×10^5 $TCID_{50}$/mL	EBV	1.0×10^5 $TCID_{50}$/mL
Human metapneumovirus (hMPV)	1.0×10^5 $TCID_{50}$/mL	CMV	1.0×10^5 $TCID_{50}$/mL
Mycobacterium tuberculosis	1.0×10^6 cells/mL	Bordetella pertussis	1.0×10^6 cells/mL
Enterovirus/Coxsackievirus B4	1.0×10^5 $TCID_{50}$/mL	Chlamydia pneumoniae	1.0×10^6 PFU/mL
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL	Haemophilus influenzae	1.0×10^6 cells/mL
Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL	Legionella pneumophila	1.0×10^6 cells/mL
Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	Mycoplasma pneumoniae	1.0×10^6 U/mL
Human parainfluenza virus1	1.0×10^5 $TCID_{50}$/mL	Streptococcus pneumoniae	1.0×10^6 cells/mL
Human parainfluenza virus2	1.0×10^5 $TCID_{50}$/mL	Influenza A	1.0×10^5 $TCID_{50}$/mL
Human parainfluenza virus3	1.0×10^5 $TCID_{50}$/mL	Rhinovirus	1.0×10^5 PFU/mL
Human parainfluenza virus4	1.0×10^5 $TCID_{50}$/mL	Staphylococcus aureus	1.0×10^6 org/mL
Streptococcus pyogenes (group A)	1.0×10^6 cells/mL	Influenza B	1.0×10^5 $TCID_{50}$/mL
Staphylococcus epidermidis	1.0×10^6 org/mL	E. coli	1.0×10^7 cells/mL
Respiratory Syncytial Virus A	1.0×10^5 PFU/mL	Candida albicans	1.0×10^6 cells/mL

【INTERFERENCES】

The following substances have been tested and no interference was found with the COVID-19 Antigen Rapid Test Kit(Colloidal Gold):

Zincum gluconium (i.e. Zicam): 5% w/v	Cromolyn: 15% v/v	Whole Blood: 1% v/v
Benzocaine, Menthol: 0.15% w/v	Alkalol: 10% v/v	Phenylephrine: 15% v/v
Galphimia glauca, Sabadilla: 20% v/v	Oxymetazoline: 15% v/v	Tobramycin: 0.0004% w/v
Sodium Chloride (i.e. NeilMed): 5% v/v	Fluconazole: 5% w/v	Fluticasone Propionate: 5% v/v
Tamiflu (Oseltamivir Phosphate): 0.5% w/v	Phenol: 15% v/v	Mupirocin: 0.25% w/v Mucin: 2% w/v

【WARNINGS AND PRECAUTIONS】

1. Children under 18 years of age should be assisted by an adult.
2. Read the Instructions for Use (this leaflet) carefully before use.
3. Do not re-use. Do not drink any liquid in the test kit.
4. Do not use the test kit beyond the expiry date.
5. Do not use the test kit if any of the kit components are missing, broken, or unsealed.
6. Store the test kit at 2-30 °C. Do not freeze.
7. Handle all specimens as potentially infectious.
8. The specimens should be tested immediately after collection.
9. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
10. Correct specimen collection is a quite important step during the testing procedures. Make sure to collect enough specimens with the anterior nasal swab.
11. The test should be used at room temperature (8-30 °C). If the test has been stored in a cool area (less than 8 °C), leave it at normal room temperature for 30 minutes before using.
12. Use the anterior nasal swab provided in the test kit to ensure optimal performance of the test.
13. Apply the drops of test specimen only to the specimen well (S) on the test card.
14. Too many or too few drops of extracted specimen may result in invalid or incorrect test result.
15. The specimen collection procedures may be uncomfortable. Do not insert the anterior nasal swab too much deeper, please stop the test if you feel strong resistance or pain.
16. Keep the test kit and kit components out of the reach of children and pets before and after use.
17. The extraction solution in extraction tube contains chemical components. Direct contact should be avoided and eat is prohibited. If the solution contacts the skin or mucosa or eye, please flush with copious amounts of water. Please contact your family doctor or professional or seek medical advice if necessary.
18. User should not take any decision of medical relevance without first consulting his or her medical practitioner.

【LIMITATIONS】

1. The components of this test kit are to be used exclusively for the qualitative detection of SARS-CoV-2 antigen in anterior nasal swab specimens. Other specimen types may lead to incorrect results and must not be used.
2. The test kit is used for rapid detection of suspected COVID-19 cases within the first 7 days of symptom onset, so asymptomatic individuals may get a false-negative test result.
3. Failure to follow the instructions for test procedures and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A negative test result may occur if the specimen was collected or extracted improperly. A negative test result does not eliminate the possibility of SARS-CoV-2 infection and should be confirmed by a molecular assay.
5. Improper storage, collection, or even freezing and thawing of the specimen can lead to inaccurate test results.
6. Positive test results do not rule out co-infections with other pathogens.
7. If the viral load of the specimen is below the detection limit of the test, the test may produce a negative result.
8. Test results must be evaluated in conjunction with other clinical data available to the physician laboratory test results.
9. The amount of antigen in a sample may decrease as the duration of illness develops. Specimens collected after 5-7 days of symptom onset of illness are more likely to be tested negative compared to a molecular assay.

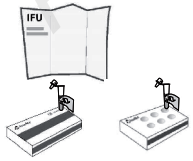
【STORAGE AND SHELF LIFE】

1. The test kit should be stored at 2-30 °C, and the shelf life is 18 months.
2. After the aluminum foil pouch is unsealed, it is recommended to use the test card within 1 hour at room temperature.
3. The extraction solution is recommended to be used within 1 hour after opening at room temperature.

【PREPARATION BEFORE TEST PROCEDURES】

1. Make sure all kit components are equilibrated to room temperature on the flat and clean surface.
2. Make sure the kit components are complete without any missing or damaged after opening.
3. Make sure to check the kit expiry date before testing.
4. Make sure to wash or sanitize your hands, and make sure they are dry before starting.
5. Make sure to prepare the following materials required but not provided in the kit.
   - Timer (watch)
   - Waste container

【OPERATION OF TEST PROCEDURES】



1. Take out the Instructions for Use and read it carefully.

2. Take out the tube rack and assemble it. Gently press one tube rack well and place the extraction tube into the tube rack.

Note: For specification of 1 Test/Kit, tube rack is on the kit packaging.

3. Peel off the foil seal from the top of extraction tube, being sure to keep the extraction tube upright.

Caution: Safely peel off the foil seal away from your eyes and face. Do not splash the liquid.

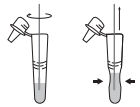
4. Find the anterior nasal swab in the sealed wrapper. Identify the soft fabric tip of the swab. Peel off the swab packaging and gently take out the swab.
Caution: Never touch the soft fabric tip of the swab with your fingers to avoid pollution.

5. Specimen Collection

5.1 Tilt your head back 70 degrees. Gently insert the anterior nasal swab into one nostril of the user. The swab tip should be inserted about 2.5 cm from the edge of the nostril. When children are tested the swabbing depth should be less than in case of testing adults.

5.2 Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.

5.3 Use the same swab to repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. Withdraw the swab from the nasal cavity.



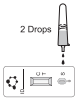
6. Specimen Handling

6.1 Insert the anterior nasal swab into extraction tube. Stir the swab more than 5 times. Leave the swab in extraction tube for about 1 minute.

6.2 Squeeze the swab against the inner wall of extraction tube to release the liquid as much as possible when you remove the swab. Dispose of the test swab with normal household waste in accordance with applicable local regulations.

7. Press the cap onto the extraction tube tightly.

8. Unseal the foil pouch and take out the test card. Place the card on the flat surface.



9. Apply 2 drops of extracted specimens to the specimen well of the test card by gently squeezing the extraction tube, and then start timing.

10. Read the test results in 15-20 minutes, and test results after 20 minutes may not be accurate.

【WASTE DISPOSAL AFTER TEST PROCEDURES】

1. Place the used test card, extraction tube with extraction solution and anterior nasal swab in a disposal bag and seal the disposal bag.

2. Dispose all the used devices in compliance with the local regulations.

3. Wash or sanitize your hands again.

【INTERPRETATION OF TEST RESULT】

Positive

Positive:
If both the control line (C) and the test line (T) appear within 15-20 minutes, the result is positive.
Caution: No matter how faint the colored band is in the test line (T), the result should be considered as positive.

Negative

Negative:
If there is only a control line (C) and test line (T) is colorless within 15-20 minutes, the test result is negative.

Invalid

Invalid:
If the control line (C) is not observed within 15-20 minutes, the test is invalid. And the test shall be conducted again with a new test kit.

【FREQUENTLY ASKED QUESTIONS (FAQ)】

1. When can/should I test myself?
You can have a test on yourself whether you have symptoms or not, but asymptomatic individuals may get a false-negative test result. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated according to local regulations.
2. What should I pay attention to in order to have the optimal test result?
Always follow the instructions for use correctly. Apply two drops of extracted specimen from the extraction tube into the specimen well of the test card. Too many or too few drops can lead to an incorrect or invalid test result.
3. The test strip is very discolored. What may be the reasons?
The reason for a clearly visible discoloration of the test strip is that too many drops has been dispensed from the extraction tube into the specimen well of test card. The indicator strip can only hold a limited amount of liquid. If the control line (C) does not appear or the test strip is very discolored, please repeat the test according to the instructions for use.
4. I have taken the test, but the control line (C) doesn't appear. What should I do?
According to the instructions for use, this test result is invalid. Please repeat the test according to the instructions for use.
5. I am not sure about reading test result. What should I do?
Read the instructions for use again, and if this doesn't help, please contact the nearest health facility recommended by your local authorities for help.
6. If my test result is positive, what should I do?
There is possibility of hospitalization, complications and even death after infection with SARS-CoV-2. You should immediately contact the nearest health facility recommended by your local authorities.
7. If my test result is negative, what should I do?
You also need to obey the local regulations. If you experience symptoms such as fever, headaches, migraines, loss of sense of smell and taste, contact the nearest health facility recommended by your local authorities.
8. Will this Test Hurt?
No, the anterior nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and ask for help from a healthcare provider.

【ACCESSORY】

The information for anterior nasal swabs is as below:

Manufacturer	EC-representative	CE-Mark
Jiangsu HanHeng Medical Technology Co., Ltd. 16-b4, No.1, Qingyang North Road, Tianning District, Changzhou City, Jiangsu Province, P.R.China	Luxus Lebenswelt GmbH Kochstr.1, 47877, Willich, Germany	CE 0197 acc. 93/42/EEC
Jinan Babio Biotechnology Co., Ltd. 303, Building 5 of SME Industrialization Base of Biomedical Park, 1777 Dazheng Road, High-tech Zone, Jinan City, 250101, Shandong Province, China	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany	CE 0413 acc. 93/42/EEC
Shenzhen Kangdaan Biological Technology Co. Ltd. 3rd floor, Building A2, Shunheda factory, Liuxiandong industrial zone, Xilli street, Nanshan district, Shenzhen, China.	Share Info Consultant Service LLC Repräsentanzbüro Heerdter Lohweg 83 40549 Düsseldorf, Deutschland	CE 0197 acc. 93/42/EEC
BioTeke Corporation (Wuxi) Co., Ltd. 4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, Jiangsu CN 214174	SUNGO Europe B.V. Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands	CE 2797 acc. 2017/745

【EXPLANATION FOR SYMBOLS】

	Expiry date	LOT	Batch Number		Consult Instructions for use
	Test (s) per kit	2°C 30°C	Store at 2-30°C	REF	Catalogue Number
	Manufacturer	CE 1434	CE Mark		Do not reuse
IVD	In Vitro diagnostic use	EC REP	European Authorized Representative		keep dry
	Do not use if package is damaged		Keep away from sunlight		

【Issue Date and version No. of the Instruction for use】

Issue Date: May 21, 2022

Version 5.0

Xiamen AmonMed Biotechnology Co., Ltd.
Address: Unit 503, 120 Xinyuan Road, Haicang District, Xiamen, Fujian, China.
Manufacturing address: 5F and 6F, No. 253, Duiying South Road, Jimei District, Xiamen City, Fujian Province, China

EC REP **SUNGO Europe B.V.**
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands