COVID-19 Antigen Rapid Test Kit (Colloidal Gold)

Instructions for Use

—For use at home self-test or Non-professional
—For use with nasal cavity (anterior nasal) swab specimen
—For *In Vitro* Diagnostic Use Only
—Please read the instructions carefully before use

INTENDED USE

COVID-19 Antigen Rapid Test Kit (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 Antigen (Nucleocapsid protein, N protein) which is in nasal cavity (anterior nasal) swab specimen. The test kit is intended for non-professional test or home test. Children and teenagers under the age of 18 must be tested with the assistance of legal guardians or authorized personnel. This product can detect symptomatic or asymptomatic infections.

SUMMARY

COVID-19 is an acute respiratory infectious disease, People are prone to infection generally. Currently, the main cause of COVID-19 infection is contact with someone who is already infected with the SARS-CoV-2, and asymptomatic infected people may also transmit the virus. Studies have shown that symptoms of infection generally appear within 14 days, with most occurring within 3 to 7 days after infection. The main symptoms are fever, fatigue, loss of smell or taste, and a dry cough. In some cases, a stuffy nose, runny nose, muscle pain and diarrhea can also occur. Once infected with the COVID-19, you must self-isolate and follow the advice of your family doctor or seek medical treatment. Some infected people will have some complications, which may lead to death if they are not treated in time.

PRINCIPLE

COVID-19 Antigen Rapid Test Kit (Colloidal Gold) adopts immune lateral chromatography technology and double antibody sandwich method to detect the SARS-CoV-2 antigen nucleocapsid protein. If the test specimen contains SARS-CoV-2 antigen, the result is positive and both test line (T) and control line (C) will appear; if the sample does not contain

SARS-CoV-2 antigen or the SARS-CoV-2 antigen is not detected, the result will be negative and test line (T) will not appear, only the control line (C) will appear.

MAIN KIT COMPONENTS

Catalogue number	XJ-ZC-411	XJ-ZC-412	XJ-ZC-413	XJ-ZC-414
Specification	1 Test/Kit	2 Tests/Kit	5 Tests/Kit	25 Tests/Kit
Test device (Include extraction solution and test strip)	1	2	5	25
Disposable swab	1	2	5	25
Biohazard Waste Bag	1	2	5	25
Instructions for Use	1	1	1	1

Materials required but not provided: Timer

STORAGE CONDITIONS AND SHELF LIFE

The test kit should be Stored conditions of 2°C~30°C, dry and out of direct sunlight. The shelf life of the kit is 18 months.

Don’t freeze the kit or its components.

For the kit expiration date, please refer to the product label.

PRECAUTIONS

1. Please read the Instruction for Use carefully before the test, and strictly operate in accordance with the requirements of the Instruction for Use for test.
2. Keep the product or product components out of the reach of children and pets before and after use.
3. The packaging of the test card contains desiccant; it is strictly inedible.
4. Do not use expired products.
5. The kit should be stored in accordance with the storage conditions in the Instruction for Use. Do not use the kits that are not stored in accordance with the requirements.
6. All components and samples need to be equilibrated to room temperature (15~30°C) before use.
7. It is recommended to use protective equipment such as gloves when testing.
8. Do not eat, drink or smoke in the sample processed or tested area.
9. Do not use components that have been opened or tampered.

10. The test device is sealed in aluminum foil bag. If the aluminum foil bag is damaged or opened, please do not use it.
11. The swab is a sterile product. If the package is damaged or opened, please do not use it.
12. The use of swabs should strictly follow the Instruction for Use, otherwise it may cause nasal bleeding, swab breakage or retention.
13. Do not immerse the swab in the extract or other liquid before inserting the swab into the nasal cavity.
14. Do not touch the soft end of the swab when handling swab samples.
15. To get correct results, correct sample collection and processing are essential.
16. Do not mix components/kits of products with different production batch numbers.
17. All kits/components are disposable, do not use with multiple samples or reuse reagent kits/components.
18. It is recommended to communicate with family doctors or professionals before decided to implement treatment or manage decisions, and do not conduct drug treatment, harm yourself or harm others without authorization.
19. The used kit components and samples can be placed in plastic bags together with ordinary household garbage. If the test result is positive, the relevant waste components and samples should be handled carefully, and the work surface should be thoroughly cleaned and disinfected to ensure the sanitation of the place. If local laws or regulations have special regulations on waste, local laws and regulations should be strictly abided by.
20. In the view of the global pandemic of the COVID-19, all actions should comply with the current measures and regulations of your country/region, scientifically implement prevention and control measures, and effectively protect yourself and others.

LIMITATION

1. For *In Vitro* Diagnostic Use Only.
2. This kit is only used for the detection of human anterior nasal swab specimens. Other specimens may lead error results.
3. This kit only used for qualitative testing and cannot determine the concentration of the COVID-19 antigen in the sample.
4. Failure to follow the operating procedures may affect the performance of the test and/or cause the test results to be invalid.
5. If the test result is negative but the clinical symptoms keep exist, it is recommended to repeat the test or use other clinical test methods. If the result is still negative, it may be caused by virus concentration which lower than the detection of limit or unstandardized/insufficient sample collection.
6. A negative result cannot rule out the possible of COVID-19 infection, especially for those who have contact with COVID-19 infected person. It is recommended to use PCR for follow-up

testing to rule out the infection. Individuals who have symptoms of COVID-19 but have a negative test result should comply with the restrictions of the local country/region until the infection is ruled out.

7. A positive result does not rule out the possibility of co-infection with other pathogens.

8. Restricted by factors such as test reagent methodology, sample collection, sample processing, tester infection time and tester's individual differences, false positive or false negative test results may occur.

9. This test results cannot be the base for implemented treatment or management decision-making. It is recommended to communicate with family doctors or professionals in advance or seek medical treatment.

TEST PROCEDURE

Please read the Instructions for Use carefully and perform each step as required. This process is very important for the accuracy of the results.

Ⅰ Preparatory work

1. Please use the kit at room temperature (15°C~30°C). If the kit was previously stored under low temperature (lower than 15°C), please leave it at room temperature for 30 minutes before use.

2. Wash your hands thoroughly (at least 20 seconds) with soap and warm water or hand sanitizer. This step ensures that the kit is not contaminated, and then please dry your hands.

3. Check the contents of the kit and prepare necessary items for testing to ensure that there is no damage or breakage, and all materials are ready.

			
Test device (sealed container)	Disposable swab (sealed container)	Biohazard Waste Bag	Timer

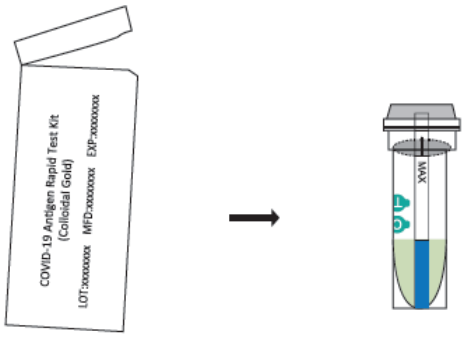
Warning!

—If the sealed package is damaged, do not use it and replace a new kit.

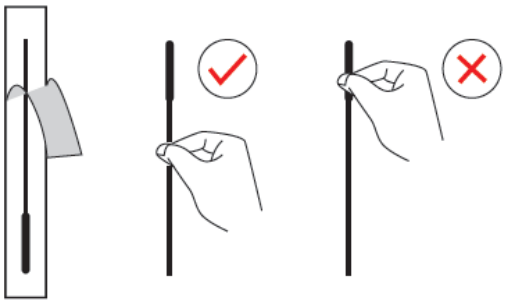
—If you have cough symptoms, please test in private.

Ⅱ Sample collection and processing

1. Open the aluminum foil bag of and take out the device. Lay the device at flat platform or holder (attached with the kit).

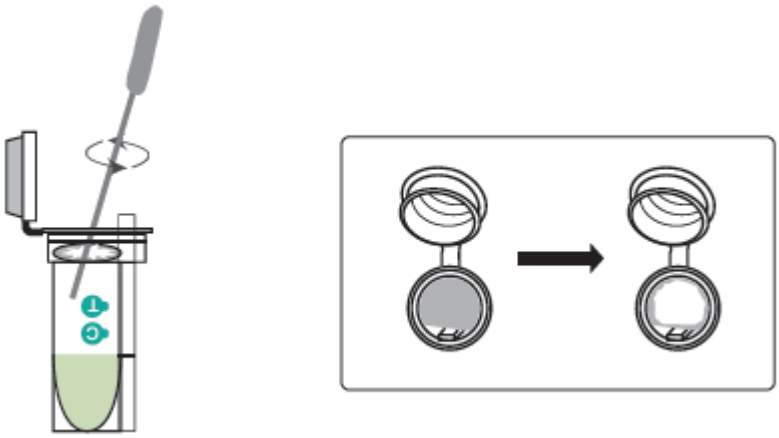


2. Open the package at the end of the swab rod and take out the swab.



3. Open the cover of the detection device and take out the desiccant of device.

4. Use the end of the swab rod to puncture the sealing aluminum film and remove it. Place the detection device at flat platform or holder (attached with the kit).

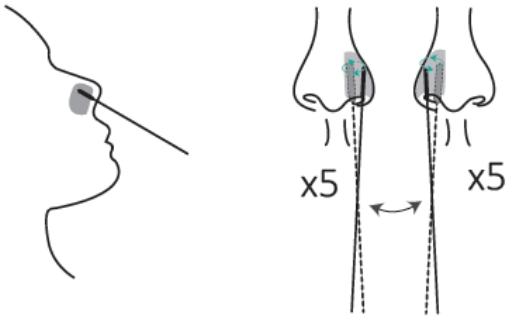


5. As picture show, wipe both nostrils with the swab.

(1) Insert the soft end of the swab into the nostril less than 1 inch (usually about 0.5 to 0.75 inches).

(2) Use a medium force to gently rotate and wipe the nostrils, at least five times.

(3) Using the same swab, repeat another nostril sample.



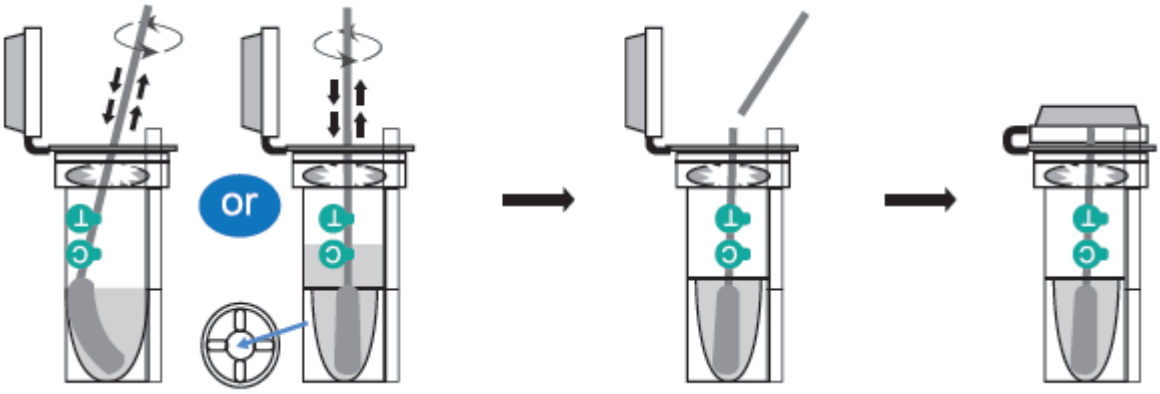
Warning!

—Do not insert too deep into the nostril, otherwise it may cause nasal bleeding, swab breakage or retention.

—False negative results may occur if there are fault when nasal swab collected.

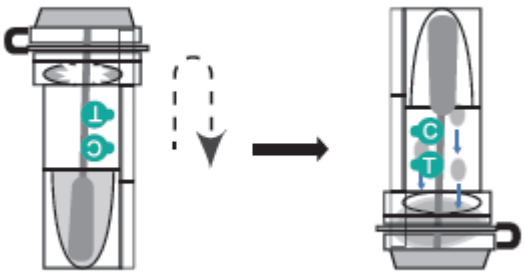
—Children and teenagers under the age of 18 must be tested with the assistance of legal guardians or authorized personnel.

6. Insert the soft end of the swab into the extraction solution of device, gently press the soft end of the swab against the inner wall of the detection device and rotate it clockwise or counterclockwise about 10 times. Place the cut point of the swab rod close to the open side of the tube, gently break the swab rod, and leave the soft end of the swab in the tube. Press the tube cover firmly until the second buckle is closed for use.



Ⅲ Sample testing

1. Gently shake the detection device, and gently shake the detection device after inverting the detection device to ensure that all the sample mixture flows into the bottom of the tube cover and place it on a horizontal table.



2. Start timing after inversion, wait for 15 minutes to interpret the result and do not interpret before 15 minutes or after 20 minutes.

Warning!

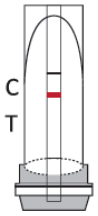
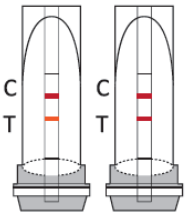
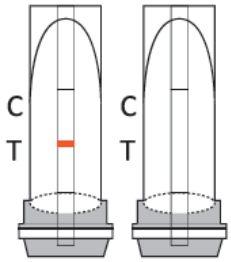
1.Please keep the table steady after inverting.

2. Do not move or invert the detection device before the interpretation time reach, to avoid to affect the detection results.

3. After test, put all the test components into the biohazard waste bag, and should be dispose with household-waste according to local regulation.

4. Rewash hands thoroughly (at least 20 seconds) with soap and warm water/hand sanitizer.

INTERPRETATION OF THE RESULTS

<table>
<tr><td>Negative：
The quality control line (C line) appears red band, while the test line (T line) doesn’t appear red band.</td><td> 
</td></tr>
<tr><td>Positive：
Both the quality control line (C line) and the test line (T line) appear red bands.</td><td> 
</td></tr>
<tr><td colspan="2">Warning！
Regardless of the shades of color, the result should be judged as positive result.</td></tr>
<tr><td>Invalid：
Once the red line in the control line (C line) region doesn’t appear which will be treated as invalid.</td><td> 
</td></tr>
<tr><td colspan="2">Warning！
Invalid results may indicate that you did not strictly follow the operation steps of instruction for use. Please read the instruction for use carefully again and select a new kit for testing again.</td></tr>
</table>

PROCESSING OF TEST RESULTS

■ **If the test result is positive：**

— COVID-19 infection is present currently

— Contact your doctor or local health department immediately.

— Comply with the self-quarantine requirement and protection guidelines in your area.

— Carry out PCR test for confirmation.

■ **If the test result is negative**:

— You need to continue to take measures related to contact with others and self-protection.

— Even if your test result is negative, it is also possible that there is an infection.

— If you still suspect, please repeat the test after 24h. On account of the coronavirus cannot be accurately detected at every stage of infection.

■ **If the test result is invalid**:

— It may be caused by incorrect operation in the detection process.

— Please repeat the test.

— If the test result is still invalid, please contact your doctor or COVID-19 testing center.

QUALITY CONTROL

The quality control line is a key point of test kit and is used to control the procedure. The quality control line appears, which indicates that the test has been performed correctly and the test kit has reacted

FREQUENTLY ASKED QUESTIONS (FAQ)

1. What are the known or potential benefits of product testing?

-- The test results can help your family doctor or professional make accurate or effective recommendations.

-- Test results may help limit the spread of COVID-19 to your family and others in your community.

2. What are the known or potential risks in product testing?

-- Discomforts may occur during specimen collection.

-- Incorrect test results may be obtained.

3. When should/can I test myself?

You can test yourself when you have suspected symptoms of COVID-19. Studies have shown that COVID-19 infected person have a high virus load in the first four days of illness, making it easier to detect.

4. What's the difference between Antigen and Molecular test?

Currently, there are several SARS-CoV-2 test methods. Molecular test (also known as PCR test) detect the genetic material of the virus, and Antigen test detect the proteins in the virus.

5. What factors will affect the test results? What should I pay attention to?

-- For anterior nasal swab specimen only.

-- Test immediately after sample collection.

-- Strictly follow the Instructions for Use.

6. No red line band on test card or abnormal fluid flow? What is the reason?

It should be clear that the test result is invalid. The reasons are as follows:

-- The table on which the test card is placed is not smooth, affecting the flow of liquid.

-- Drop sample volume does not meet the requirements specified in the Instructions for Use.

-- The test card is damp.

7. I have taken the best, but I don't see the control line (C). What should I do?

Your test result is invalid, please repeat the test strictly according to the Instructions for Use.

8. Unsure about the test result, what should I do?

For uncertain results can be retested, if you're still unsure of the test result, please contact the nearest medical institution according to the advice of your local government.

9. If result is positive, what should I do?

If your test result is positive, you may be infected with COVID-19. You should take the necessary measures (such as quarantine, report, retest, etc.) as required by the local government, and contact the nearest medical institution for next action.

10. If result is negative, what should I do?

If the test kit only clearly shows the control line band, this may mean that the test result is negative or that the virus is too low to be detected. If you still have COVID-19 symptoms (headache, fever, loss of smell or taste, etc.), please consult your family doctor or medical institution recommended by local government.

ADVERSE EVENT REPORT

For the COVID-19 antigen self-testing, the regulatory authorities in various countries may have different regulatory requirements, and have their own reporting channels for adverse event reports. Therefore, different countries/regions should pay attention to the official websites of their respective regulatory authorities.

In case of adverse vents reporting, please cooperate with local distributors.

Taking Germany and France as example, the official channels are as follows:

Germany
Plateform of BfArM : https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/Spezialthemen/Antigentests/_node.html Adverse Health Event Reporting Portal: https://www.bfarm.de/DE/Medizinprodukte/Antraege-und-Meldungen/_node.html
France
Plateform of Health Ministry: https://covid-19.sante.gouv.fr/tests **Adverse Health Event Reporting Portal:**

https://signalement.social-sante.gouv.fr/psig_ihm_utilisateurs/index.html#/accueil

PERFORMANCE CHARACTERISTICS

- **Limit of detection**

The limit of detection concentration is 1.6×10^2 $TCID_{50}$/mL.

- **Clinical performance**

The clinical performance characteristic of the COVID-19 Antigen Rapid Test Kit (Colloidal Gold)was established with 500 anterior nasal swab specimens. The anterior nasal cavity samples of the donors used Xiamen Hopegen COVID-19 Antigen Rapid Test Kit (Colloidal Gold), parallel detect with the CE-marked nucleic acid detection reagents, the test results are summarized as follows:

Hopegen Medical	Reference PCR result			Category	Result	95% C.I.
	Positive	Negative	Total	PPA	91.00%	83.77%~95.19%
Positive	91	0	91	NPA	100.00%	99.05%~100.00%
Negative	9	400	409	PPV	100.00%	95.95%~100.00%
Total	100	400	500	NPV	97.80%	95.87%~98.84%
				OPA	98.20%	96.61%~99.05%

- **Cross reaction**

None of the following microorganisms or pathogens evaluated with the COVID-19 Antigen Rapid Test Kit (Colloidal Gold) were found to affect test performance: Influenza A virus H1N1 (Brisbane_59_2007), Influenza A virus H3N2 (A_Brisbane_10_2007), Influenza B Virus (B_Florida_4_2006,Yamagata Lineage), Influenza B Virus (B_Hong Kong_330_2001, Victoria Lineage), Human Coronavirus 229E, Human Coronavirus OC43, Human Coronavirus NL63, Human Coronavirus HKU1, Parainfluenza Virus Type 1, Parainfluenza Virus Type 2, Parainfluenza Virus Type 3, Parainfluenza Virus Type 4B, Adenovirus 1 (Species C), Respiratory Syncytial Virus Type A, Rhinovirus Type 1A, Rhinovirus B70, Adenovirus Culture Fluid 7A （Species B）, Enterovirus Type 68, Coronavirus-SARS Stock, MERS-CoV, Chlamydophila

pneumoniae, Mycoplasma pneumoniae M129, Bordetella pertussis A639, Haemophilus influenzae Type B, Candida albicans Z006, Staphylococcus aureus MSSE, Streptococcus pneumoniae Z022, Streptococcus pyogenes Z018, Legionella pneumophila.

- **Interference Substances**

None of the following substances evaluated with the COVID-19 Antigen Rapid Test Kit (Colloidal Gold) at the concentrations listed below were found to affect test performance: Mucin 5%, Whole Blood 5%(V/V), α-Interferon 200000IU/mL, Zanamivir 100ng/mL, Ribavirin 20μg/mL, Oseltamivir 5μg/mL, Peramivir 0.2mg/mL, Lopinavir 8mg/mL, Ritonavir 200μg/mL, Arbidol 4μg/mL, Levofloxacin 20μg/mL, Azithromycin 2.0μg/mL, Ceftriaxone 0.8mg/mL, Meropenem 1.0mg/ml, Tobramycin 2ng/mL, Phenylephrine 20μg/mL, Oxymetazoline 0.1mg/mL, Beclomethasone 0.1mg/mL, Dexamethasone 2mg/mL, Flunisolide 0.1mg/mL, Triamcinolone Acetonide 10.0ng/mL, Budesonide 2.00ng/mL, Mometasone 10ng/mL, Fluticasone 50μg/mL, Histamine Hydrochloride 10ng/mL, Sodium Chloride 5%.

- **Hook effect**

  Within the concentration of 3.4×10^5 $TCID_{50}$/mL for cell culture medium of SARS-CoV-2 Antigen, the test results of this product showed no Hook effect.

LITERATURE REFERENCES

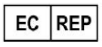
[1] NMPA. The Technical Key Points for Coronavirus (COVID-19) Antigen-antibody Detection Reagent Registration Review (Trial). (2020).

[2] Xu Chao, Li Ran. Analysis on the Risk Management of in Vitro Diagnostic Reagents[J]. China Medical Device Information. 2020, 26(13):8-10.

[3] Wu Jinhui, Meng Li. Immunocolloidal Gold Technology: Advances and Application[J]. Chinese Agricultural Science Bulletin. 2019, 35(13): 146-151.

SYMBOLS

Symbol	Used for	Symbol	Used for	Symbol	Used for

	Consult instructions for use		Tests per kit		Manufacturer
	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
	Store at 2℃～30℃		Catalogue number		Batch code
	Authorized Representative in the European Community		Caution		Keep dry
	Don’t use the product when the package is damaged		Biological risks		

Xiamen Hopegen Medical Technology Co., Ltd.

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Tel: +86-592-3755118

SUNGO Europe B.V

Address：Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Suppliers of disposable sterile swab

Zhejiang Gongdong Medical Technology Co.,Ltd.

Address：No.10 Beiyuan Ave., Huangyan,318020 Taizhou, Zhejiang, PEOPLE’S REPUBLIC OF CHINA 318020

Shanghai International Holding Corp. Gmbh (Europe)

Address：Eiffestrasse 80,20537 Hamburg,Germany

CE 2934

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