COVID-19 Antigen Rapid Test (Colloidal Gold)

Instructions For Use

【PRODUCT NAME】

COVID-19 Antigen Rapid Test (Colloidal Gold)

【SUMMARY】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease caused by the novel coronaviruses (SARS - CoV - 2). People are generally susceptible. Currently, the user 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, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

【PACKING SPECIFICATIONS】

1 Test/Kit, 5 Tests/Kit, 20 Tests/Kit, 25 Tests/Kit.

【INTENDED USE】

The COVID-19 Antigen Rapid Test (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of SARS - CoV - 2 in nasopharyngeal swab, anterior nasal swab and oropharyngeal swab specimen. It provides only an initial screening test result and more specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection.

【PRINCIPLE】

The COVID-19 Antigen Test (Colloidal Gold) is a qualitative membrane strip based on immunoassay for the detection of the nucleocapsid protein antigen from SARS-CoV-2 in swab specimen. In this test procedure, the specimen reacts with the anti-SARS-CoV-2 antibody conjugate coated particles on the label pad, and then the mixture migrates upward on the membrane chromatographically by capillary action and reacts with the anti-SARS-CoV-2 antibody in the detection region.

If the specimen contains SARS-CoV-2, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain SARS-CoV-2, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

【KIT COMPONENTS】

Materials provided	1 Test/Kit	5 Tests/Kit.	20 Tests/Kit.	25 Tests/Kit.
Test Cassette	1 test	5 tests	20 tests	25 tests
Extraction Buffer	0.3mL/ bottle×1	0.3mL/ bottle×5	0.3mL/ bottle×20	0.3mL/ bottle×25
Swab	1 pc	5 pcs	20 pcs	25 pcs
Package Insert	1 pc	1 pc	1 pc	1 pc

Materials required but not provided
Specimen Collection Containers
Timer

【STORAGE AND STABILITY】

The test is valid for 24 months if all components are stored as packaged in the sealed pouch at 2℃~30℃.
The test must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.
Please refer to the packing of the product for the manufacture date and expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

1. COVID-19 Antigen Rapid Test (Colloidal Gold) can be applied to nasopharyngeal swab, anterior nasal swab and oropharyngeal swab.

A) Nasopharyngeal swab sample collection:

-Carefully insert the swab into the nostril, reaching the posterior wall of the nasopharynx, that presents the most secretion under visual inspection.
-Swab over the surface of the posterior nasopharynx.Rotate the swab 3~4 times

B)Anterior nasal swab sample collection:

- Tilt the head back 70 degrees. While gently rotating the swab, insert swab about 2~2.5 cm into nostril
- Rotate the swab five times against the nasal wall then slowly remove from the nostril.
- Using the same swab repeat the collection procedure with the second nostril.

C) Oropharyngeal swab sample collection:

- Tilt the head slightly and make “ahhh” sounds,exposing the pharyngeal tonsils on both sides
- Hold the swab and wipe the pharyngeal tonsils on both sides of the user with moderate force back and forth for **at least 3 times**

2. Do not return the swab to the original paper packaging.
3. For best performance, direct swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the swab is placed in a clean, unused plastic tube, preserving sample integrity, and capped tightly at room temperature (15℃ - 30℃) for up to 1 hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose the sample. A new sample must be collected for testing.
4. If specimens are to be transported, they should be packed in compliance with local regulations covering the transportation of etiological agents.

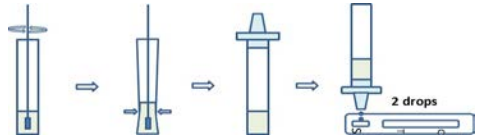
【TESTING PROCEDURE】

Please read the instructions carefully and allow the test device and specimens to equilibrate to temperature (15℃-30℃) prior to testing.

1.Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.

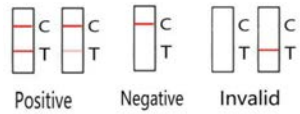
2.Open the cap or aluminium film of the tube containing the extraction buffer, put the swab with the sample into the extraction tube and rotate it 10 times, squeeze the wall of the extraction tube by hand and take out the swab, cover the cap of the extraction tube, set aside.

3.Take the test cassette from the packaging bag, place it on a table, and add 2 drops of the sample into the sample hole vertically.
4. Read the result after 15 minutes. If left unread for 20 minutes or more the results are invalid and a repeat test is recommended.



【INTERPRETATION OF RESULTS】

Positive: Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region.
***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of SARS-CoV-2 present in the specimen. Therefore, any shade of color in the test line region should be considered positive.
Negative: One colored line appears in the control region(C).No apparent colored line appear in the test line region(T).
Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



【QUALITY CONTROL PROCEDURES】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1.COVID-19 Antigen Rapid Test (Colloidal Gold) is applicable to nasopharyngeal swab, anterior nasal swab and oropharyngeal swab samples. If the sample is negative and the clinical indications suggest a Covid-19 infection, please go to the hospital for further clinical diagnosis. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 can be determined by this qualitative test.
2.A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. COVID-19 Antigen Rapid Test (Colloidal Gold) will only indicate the presence to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
4. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
5. Negative results, with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay.
6. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of SARS-CoV-2 infection.
7. The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
8. Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
9. Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

【PERFORMANCE CHARACTERISTICS】

1.Limit of Detection: The limit of detection (LOD) of COVID-19 Antigen Rapid Test (Colloidal Gold) is 100pg/mL recombinant SARS-COV-2 N protein.

2. Sensitivity and Specificity: The COVID-19 Antigen Rapid Test (Colloidal Gold) was compared with the Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit.

Nasopharyngeal Swab

Method		RT-PCR		Total Results
COVID-19 Antigen Rapid Test (Colloidal Gold)	Results	Positive	Negative	
	Positive	99	4	103
	Negative	3	496	499
Total Result		102	500	602

The total sensitivity of COVID-19 Antigen is 97.1%; 95% CI:(91.64%～99.39%)
Total specificity of COVID-19 Antigen is 99.2%; 95%CI: (97.96%-99.78%)
Total agreement rate of COVID-19 Antigen is 98.8%; 95%CI: (97.62%-99.53%)

Anterio Nasal Swab/Oropharyngeal Swab

Method		RT-PCR		Total Results
COVID-19 Antigen Rapid Test (Colloidal Gold)	Results	Positive	Negative	
	Positive	98	4	102
	Negative	4	496	500
Total Result		102	500	602

The total sensitivity of COVID-19 Antigen is 96.1%; 95% CI:(90.26%～98.92%)
Total specificity of COVID-19 Antigen is 99.2%; 95%CI: (97.96%-99.78%)
Total agreement rate of COVID-19 Antigen is 98.7%; 95%CI: (97.4%-99.42%)

3.Cross-reactivity: The following cross-reactive substances have been tested using COVID-19 Antigen Rapid Test (Colloidal Gold) and no cross-reactivity was observed.

HCoV-229E	HCoV-OC43	HCoV-NL63	MERS-CoV
HCoV-HKU1	Human RSV	Human Enterovirus	Human Rhinovirus
Human Metapneumovirus	Mycoplasma pneumoniae	Parainfluenza virus	Adenovirus
Influenza B virus (Victoria line)	H1N1 (2009) influenza virus	Influenza A H3N2 virus	Avian influenza virus H7N9
Influenza B virus (Yamagata series)	Seasonal Influenza A H1N1	Neisseria meningitidis	Streptococcus pneumoniae
Staphylococcus aureus			

4.Interfering Substances: The following compounds have been tested using COVID-19 Antigen Rapid Test (Colloidal Gold) and no interference was observed.

Interfering substances	concentration
Aspirin	30ug/dL
Ascorbic Acid	20mg/dL
Ibuprofen	200ug/dL
Bilirubin	60mg/dL
Chloramphenicol	3ug/dL

⚠【WARNINGS AND PRECAUTIONS】

1. For in vitro diagnostic use only. The test is intended for professional use only and is limited to medical institutions.
2. The storage and operation of the kit should comply with the requirements in the manual, otherwise there will be potential for influencing the test results.
3. Do not freeze reagents.
4. Reagent to avoid contamination.
5. There is animal-derived protein material in the kit, so the used product should be treated as bio-waste.
6. Materials in the testing process may be infectious. These should be treated according to laboratory biosafety requirements based on biohazardous substances.
7. Do not use the Test Device if the pouch is damaged or the seal broken.
8. The extraction buffer is not edible.

【REFERENCE】

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164. PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2.
2. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502. PMID:27012512 DOI:10.1016/j.tim.2016.03.003.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.PMID:30531947 DOI:10.1038/s41579-018-0118-9.

【EFFECTIVE DATE AND VERSION】

Effective Date:2021-11-22
Version:1

⚠ **Note**:Please refer to the table below to identify various symbols.

	Read instructions for use
	Use by
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
	Date of Manufacture
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device
Σ	Tests per kit

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