130mm

320mm

Singclean®

CE

COVID-19 Antigen Test Kit

（Colloidal Gold）

INTENDED USE

COVID-19 Antigen Test kit (Colloidal Gold) is a solid phase immunochromatographic assay for the rapid, qualitative detection of antigen to 2019 Novel Coronavirus in human saliva. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 Antigen Test kit (Colloidal Gold) must be confirmed with alternative testing method (s) and clinical findings.

PACK FORMATS

1 test/box，20 tests/box，50 tests/box，100 tests/box

INTRODUCTION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic only 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.

PRINCIPLE

The COVID-19 Antigen Test kit（Colloidal Gold） is a colloidal gold immunochromatographic assay. The test uses COVID-19 antibody (test line T) and goat anti-mouse polyclonal antibody (control line C) immobilised on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to another COVID-19 antibody conjugated with colloid gold. When the processed buffer containing the sample is added to the sample well, COVID-19 will combine with the COVID-19 antibody conjugate to form an antigen-antibody complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the COVID-19 antibody of test line T, the complex is trapped forming a burgundy colored band, it confirmed a positive test result. Absence of a colored band in the test means negative test result.

The test kit contains a quality control line (control line C), which should show a burgundy color band of goat anti-mouse polyclonal antibody combined with the colloidal gold conjugate in the gold label pad, regardless of the color on any other test line.

MATERIALS SUPPLIED

Sealed pouches each containing a test cassette, a desiccant
Sampling cotton swabs（as saliva swab）
Antigen extraction buffer
Antigen extraction tube
Paper workbench (The small one-test-box can be used as a workbench)
Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use.
DO NOT FREEZE.
Do not use beyond the expiration date.
After opening the sealed pouch, use the test as soon as possible within 60 minutes.

WARNINGS AND PRECAUTIONS

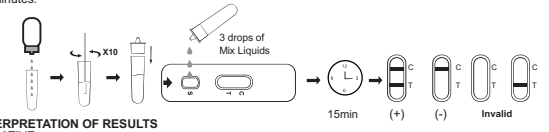
1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. These instructions must be strictly followed by a trained healthcare professional to achieve accurate results. All users have to read the instruction prior to performing a test.
3. Do not use it if the tube/pouch is damaged or broken.
4. Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
5. Avoid splashing or aerosol formation of specimen and buffer.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials (such as swab, extraction tube, test device) in a biohazard container as if they were infectious waste and dispose according to applicable local regulations.
8. Do not mix or interchange different specimens.
9. Do not mix reagent of different lots or those for other products.
10. Do not store the test kit in direct sunlight.
11. To avoid contamination, do not touch the head of provided swab when opening the swab pouch.
12. The provided swabs in the package should be used only for saliva specimen collection.
13. To avoid cross-contamination, do not reuse the swabs for specimen collection.
14. Do not dilute the collected swab with any solution except for the provided extraction buffer.
15. Test is for single use only. Do not re-use under any circumstances.
16. Do not perform the test in a room with strong air flow, such as electric fan or strong air-conditioning.

SPECIMEN COLLECTION

1. COVID-19 Antigen Test kit（Colloidal Gold）can be performed using saliva swab.
2. Testing should be performed immediately after specimen collection.
3. Bring specimens to room temperature prior to testing.
4. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
5. Avoid chewing or swallowing during the sampling period. The saliva sample should be tested immediately after sampling.

TEST PROCEDURE

Allow test cassette, Antigen extraction buffer, specimen and controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Make sure there are no food residue in the mouth before sampling. If the patient just has eaten, gargle or tooth brushing is required. Remove the swab package, keep the swab on the tongue until the tip being fully soaking by saliva (at least two minutes).
2. Place the antigen extraction tube on the workbench. Place the antigen extraction buffer bottle vertically downward, squeeze the bottle to make the buffer drip freely into the antigen extraction tube without touching the edge of the tube, and add all of the antigen extraction solution (about 450ul) to the antigen extraction tube.
3. Put the swab specimen into the antigen extraction tube pre-added with the antigen extraction buffer, and rotate the swab about 10 times while pressing the swab head against the tube wall to release the antigen in the swab, then let it stand for about 1 minute.
4. Remove the swab while squeezing the tip of the swab so that as much liquid in the swab can be discharged as possible. Dispose of used swabs in accordance with biohazard waste disposal methods.
5. Install the dripper on the antigen extraction tube and cap it tightly, and let it stand for about 1 minute.
6. Remove the test cassette from the sealed foil pouch and use it as soon as possible.
7. Place the test device on a clean and level surface.
8. Transfer 3 drops (about 100ul) of mix Liquids to the sample well of the test card (or use a pipette to add 100ul), and start the timer.
9. Wait for the test result of the reagent. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

NEGATIVE:
If only the C band is present, the absence of any burgundy color in the T band indicates that no COVID-19 antigen is detected in the specimen. The result is negative.
POSITIVE:
In addition to the presence of C band, if T band is developed, the test indicates for the presence of COVID-19 antigen in the specimen. The result is COVID-19 positive.
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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. Use fresh samples whenever possible.
2. Optimal assay performance requires strictly adherence to the assay procedure described in Instruction for use. Deviations may lead to aberrant results.
3. A negative result for an individual subject indicates absence of detectable COVID-19 antigen. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.
4. A negative result can occur if the quantity of the COVID-19 antigen present in the specimen is below the detection limits of the assay, or failed to collect the COVID-19 antigen in the saliva of the patient.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1.Clinical Sensitivity, Specificity and Accuracy
A total of 397 samples were tested in this study. The results of test reagent and control reagent both were 230 negative specimens and 167 positive specimens. The data were collected in 2021.03.02~2021.03.11, and the sensitivity and specificity calculated were valid in this study.
Table 1：COVID-19 Antigen Test Kit vs PCR

Method		PCR results		Total
		Positive	Negative	
COVID-19 Antigen Test kit	Positive	167	1	168
	Negative	0	229	229
Total		167	230	397
Sensitivity		>99.99%	95% confidence interval	97.75%~100%
Specificity		99.57 %	95% confidence interval	97.58%~99.92%
Accuracy		99.75 %	95% confidence interval	98.59%~99.96%

2.Limit of Detection (LOD)
LOD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive. Heat inactivated SARS-CoV-2 virus, with a stock concentration of 7.8 x 10^7 $TCID_{50}$/mL, was spiked into negative specimen and serially diluted. Each dilution was ran in triplicate on the COVID-19 Test Kit. The Limit of Detection of the COVID-19 Test kit is 9.975 x 10^2 $TCID_{50}$/mL (Table 2).
Table 2：Limit of Detection (LOD) Study Results

Concentration	Concentration	Concentration
9.975 x 10^2 $TCID_{50}$/mL	20/20	100%

3.High Dose Hook Effect
No high dose hook effect was observed when testing up to a concentration of 7.8 x 10^7 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus.
4.Cross Reactivity
Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the COVID-19 Test Kit.
Table 3：Cross Reactivity Study Results

Pathogens	Concentration	Influenza A H5N1 virus	1.95 x 10^5 $TCID_{50}$/mL
Human Coronavirus 229E	1 x 10^5 PFU /mL	Influenza B Yamagata	1.3 x 10^5 $TCID_{50}$/mL
Human Coronavirus OC43	1 x 10^5 PFU /mL	Influenza B Victoria	2.6 x 10^5 $TCID_{50}$/mL
Human Coronavirus HKU1	1 x 10^6 PFU/mL	Haemophilus influenzae	3.8 x 10^5 PFU/mL
Human Coronavirus NL63	1 x 10^6 PFU/mL	Rhinovirus (type 2)	1 x 10^5 PFU/mL
Adenovirus (type 5)	1.8 x 10^5 PFU/mL	Rhinovirus (type 14)	3.8 x 10^5 PFU/mL
Adenovirus (type 7)	3.2 x 10^5 $TCID_{50}$/mL	Rhinovirus (type 16)	5.5 x 10^5 PFU/mL
Adenovirus (type 18)	1.6 x 10^5 $TCID_{50}$/mL	Respiratory syncytial virus(type A-2)	2.8 x 10^5 PFU /mL
Human metapneumovirus (hMPV)	1.5 x 10^5 PFU/mL	Streptococcus pneumoniae	2.3 x 10^5 PFU/mL
Parainfluenza virus (type 1)	1.8 x 10^5 $TCID_{50}$/mL	Streptococcus thermophilus	3.8 x 10^5 PFU/mL
Influenza A H1N1 virus	2.1 x 10^5 $TCID_{50}$/mL	Mycoplasma pneumoniae	4.5 x 10^5 PFU/mL
Influenza A H3N2 virus	1.8 x 10^5 $TCID_{50}$/mL	Chlamydia pneumoniae	6.3 x 10^5 PFU/mL

5.Interfering substance
The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasopharynx, were evaluated COVID-19 Test kit at the concentrations listed below and were found not to affect test performance.
Table 4: Interfering Substance Study Results

Substance	Concentration	Ibuprofen	200μg/mL
Hemoglobin	2mg/mL	Morpholine Hydrochloride	200μg/mL
Throat lozenges	10mg/mL	Cephalexin	3μg/mL
Human Anti-mouse Antibody（HAMA）	5mg/L	Kanamycin	3μg/mL
Biotin	10mg/mL	tetracycline	3μg/mL
Mouthwash	500μl/mL	Chloramphenicol	3μg/mL
Gentamicin	3μg/mL	Erythromycin	3μg/mL
Sodium Cromolyn	120μg/mL	Vancomycin	3μg/mL
Oxymetazoline Hydrochloride	60μg/mL	Nalidixic acid	3μg/mL
Phenylephrine Hydrochloride	200μg/mL	Hydrocortisone	3μg/mL
N-Acetyl Paraaminophenol	200μg/mL	Human insulin	3μg/mL
Aspirin	30μg/mL	Beta-propiolactone	30μg/mL

6.Microbial Interference
To evaluate whether potential microorganisms in clinical samples interfere with the detection of COVID-19 Test Kit so as to produce false negative results. Each pathogenic microorganism was tested in triplicate in the presence of heat inactivated SARS-Cov-2 virus (9.975x10^2 $TCID_{50}$/mL). No cross reactivity or interference was seen with the microorganisms listed in the table below.
Table 5: Microbial Interference Study Results

Pathogens	Concentration	Influenza A H5N1 virus	1.95 x 10^5 $TCID_{50}$/mL
Human Coronavirus 229E	1 x 10^5 PFU /mL	Influenza B Yamagata	1.3 x 10^5 $TCID_{50}$/mL
Human Coronavirus OC43	1 x 10^5 PFU /mL	Influenza B Victoria	2.6 x 10^5 $TCID_{50}$/mL
Human Coronavirus HKU1	1 x 10^6 PFU/mL	Haemophilus influenzae	3.8 x 10^5 PFU/mL
Human Coronavirus NL63	1 x 10^6 PFU/mL	Rhinovirus (type 2)	1 x 10^5 PFU/mL
Adenovirus (type 5)	1.8 x 10^5 PFU/mL	Rhinovirus (type 14)	3.8 x 10^5 PFU/mL
Adenovirus (type 7)	3.2 x 10^5 $TCID_{50}$/mL	Rhinovirus (type 16)	5.5 x 10^5 PFU/mL
Adenovirus (type 18)	1.6 x 10^5 $TCID_{50}$/mL	Respiratory syncytial virus(type A-2)	2.8 x 10^5 PFU /mL
Human metapneumovirus (hMPV)	1.5 x 10^5 PFU/mL	Streptococcus pneumoniae	2.3 x 10^5 PFU/mL
Parainfluenza virus (type 1)	1.8 x 10^5 $TCID_{50}$/mL	Streptococcus thermophilus	3.8 x 10^5 PFU/mL
Influenza A H1N1 virus	2.1 x 10^5 $TCID_{50}$/mL	Mycoplasma pneumoniae	4.5 x 10^5 PFU/mL
Influenza A H3N2 virus	1.8 x 10^5 $TCID_{50}$/mL	Chlamydia pneumoniae	6.3 x 10^5 PFU/mL

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SYMBOLS USED ON PACKAGING NOTICE

EC REP	Authorized Representative		Store between 4-30°C	IVD	For in vitro diagnostic use only		Consult instructions for use
	Do not reuse	LOT	Lot Number		Don't use if package is damaged		Use by

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