Singclean®

CE 1434

COVID-19 Test Kit

(Colloidal Gold Method)

For self-testing use

INTENDEDUSE

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

PACK FORMATS

1 test/box
20 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; asymptomatically 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 Test Kit(Colloidal Gold Method) is a colloidal gold immunochromatographicassay. It detects the nucleocapsid protein on the surface of COVID-19.

The test uses COVID-19 (SARS-CoV-2) antibody (testline T) and goatanti-mouse IgG (control line C) immobilised on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to another COVID-19 (SARS-CoV-2) antibody conjugated with colloid gold and mouse IgG-gold conjugates. When the processedbuffer containingthe sample is added to the sample well, COVID-19 (SARS-CoV-2) will combine with the COVID-19antibody conjugate to forman antigen-antibody complex. This complexmigrates through nitrocellulose membrane by capillary action. When the complexmeets the line of the COVID-19 antibody of test line T, the complex is trapped forming a burgundy colored band which confirms a reactive test result. Absence of a colored band in the test region indicates a non-reactive testresult.

The testcontains an internal control (C band) which should exhibita burgundy coloredband ofthe immunocomplex goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen mustbe retested with another device.

MATERIALS COMPOSITION

COVID-19 Test Kit(Colloidal Gold Method) mainly contains the following composition:

COVID-19 antibody of Nucleocapsid protein
Goat anti-mouse IgG
Chloroauric acid
Nitrocellulose membrane

MATERIALS SUPPLIED

Sealed pouches each containinga testcassette, a desiccant
Sampling cotton swabs (for nasal cavity sampling only)
Antigen extract buffer
Antigen extraction tube
Paper workbench (The small one-test-boxcan be used as a workbench)
Instructions for use

MATERIALS REQUIREDBUTNOTPROVIDED

Timer

STORAGE AND STABILITY

The kitcanbe storedat4-30℃. Thetestdeviceis stablethroughthe expirationdate printedonthe sealedpouch.
The test device must remain in the sealed pouch until use.
Do not freeze.
Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For non-professional self-testing use. Do not use after expiration date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouchis damaged or broken.
4. Testis for single use only. Do not re-use under any circumstances.
5. Humidity and temperature can adversely affectresults.

SPECIMENCOLLECTION

1. COVID-19 Test kit (Colloidal Gold Method) can be performed using nasal cavity sampling.
2. Testing should be performed immediately after specimen collection.
3. Bring specimens to room temperature prior to testing.

TESTPROCEDURE

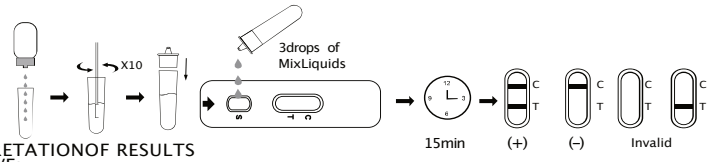
Allow test cassette, specimen, and Antigen extract buffer control to equilibrate to room temperature (15-25°C) prior to testing.Please wash and disinfectyour hands before the test.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained ifthe assay is performed within one hour.
2. Place the testdevice on a clean and level surface.

Operation process:

1.Remove the secretions on the surface ofthe anterior nasal cavity, keep the head slightly tilted,and gently and slowly insertthe swabthroughthe nasal cavity (about2-4cm), Rotate gently 5times, andgently rotate to remove the swab.

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 extraction tube withouttouching the edge of the tube, and add 6 drops (about 200ul) to the extraction tube.
3. Put the swab specimen into the extraction tube pre-added with the antigen extraction buffer, and rotate the swababout10times while pressingthe swabheadagainstthe tube wall to release the antigen inthe swab, then let it stand for about 1 minute.
4. Remove the swab while squeezing the tip ofthe swab so that as much liquid in the swab can be discharged as possible.
5. Install the dripper on the extraction tube and cap it tightly,and let it stand for about1 minute.
6. Open the aluminum foil bag and take out the test card, add 3 drops (about 100μl) into the sample hole of the test card (or use a pipette to add 100μl), and start the timer.
7. Wait for the colored line to appear. The result should be read in 15 minutes. Do notinterpretthe resultafter20 minutes.



INTERPRETATIONOF RESULTS

NEGATIVE:

If only the C band is present, the absence of any burgundy color in the T band indicates that no COVID-19 (SARS-CoV-2) antigen is detected inthe specimen. The result is negative.

If the test result is negative:

Continue to follow all applicable rules regarding contactwith others and protective measures.
Even if the testis negative, an infection may be present.
In case of suspicion, repeatthe test after 1 -2 days, because the Coronavirus cannotbe accurately detected at all stages of infection.

COVID-19 positive:

If the C and T band is present, the test indicates for the presence of COVID-19 (SARS-CoV-2) antigen in the specimen. The resultis COVID-19positive.
There is currently a suspicion of a COVID-19 infection.
Contact physician/family physician or local health department immediately.
Follow local guidelines for self-isolation.
Have a PCR confirmatorytest performed.

INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons forcontrol line failure. Review the procedure andrepeatthe testwith a new testcassette. Ifthe problem persists, discontinue using the testkit immediately and contact your local distributor.

In case of an invalid test result:

Possibly advance warning due to incorrecttest performance.
Repeatthe test.
If test results are still invalid, contact a physician or a COVID-19-TestCenter.

LIMITATIONS

1. Use fresh samples whenever possible.
2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. A negative result for an individual subjectindicates absence of detectable COVID-19 (SARS-CoV-2) antigen. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.
4. A negative resultcan occur if the quantity ofthe COVID-19 (SARS-CoV-2) antigen presentin the specimen is below the detection limits of the assay, or failed to collect the COVID-19 (SARS-COV-2) antigen in the nasal cavity of the patient.
5. The test kit provides a self-assessment. A conformed diagnosis should only be made by a physician after all clinical and laboratory findingshave been evaluated.
6. Only use for in vitro diagnostic, and cannot reused.
7. The antigen extract buffer is used to extract specimens, and shall not be used internal or external by humans oranimals.Swallowingwillcauseaserious accident. Ifhappens,please seekmedicalattentionimmediately.The antigen extract is irritating to eyes and skin, if splashed into eyes accidentally, please rinse with water soon. If necessary, consult a doctor and maintain ventilation during the procedure.
8. This productis only used for self-testingby people aged 18-60.Elderly orminors please use itwith theirguardian.

PERFORMANCE CHARACTERISTICS

1.Clinical Sensitivity, Specificity andAccuracy

The results ofthe COVID-19 Test Kit（Colloidal Gold Method) were compared to results of RT-PCR assays for SARS-CoV-2 in nasal swab specimens. A total of 499 nasal cavity specimens were tested in this study. The COVID-19 clinical specimens contain specimens from individuals with symptoms within 7 days. The results of testreagentand control reagentboth were 350negative specimens and 149 positive specimens. The sensitivity and specificity calculated were valid in this study.

Table 1: COVID-19 TestKitvs PCR

Method		PCR results		Total
		Positive	Negative	
COVID-19-Testkit	Positive	146	1	147
	Negative	3	349	352
Total		149	350	499
Sensitivity		97.99%	95% confidence interval	94.25% -99.31%
Specificity		99.71 %	95% confidence interval	98.40% -99.95%
Accuracy		99.20 %	95% confidence interval	97.96% -99.69%

Limit of Detection (LOD)

LOD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates testpositive. HeatinactivatedSARS-CoV-2virus, witha stockconcentration of$7.8x10^7$ $TCID_{50}$/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 9.75 $x10^2$ $TCID_{50}$/mL (Table 2).

Table 2: Limit of Detection (LOD) Study Results

Concentration	Concentration	Concentration
9.75 $x10^2$ $TCID_{50}$/mL	20/20	100%

2.High Dose HookEffect

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.

3.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 TestKit.

Table 3: Cross Reactivity Study Results

PPathogens	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 10^5 PFU/mL	Haemophilus influenzae	3.8 x 10^5 PFU/mL
Human Coronavirus NL63	1 x 10^5 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

4.Interfering substance

The followingsubstances, naturally presentinrespiratory specimensorthatmay beartificially introducedinto the nasopharynx, were evaluated COVID-19 Testkit at the concentrations listed below and were found notto affect test performance.

Table 4: InterferingSubstance Study Results

Substance	Concentrazione	Ibuprofen	200μg/mL
Hemoglobin	2mg/mL	Morpholine Hydrochloride	200μg/mL
Mucin	2mg/mL	Cephalexin	3μg/mL
Human Anti-mouse Antibody（HAMA）	5mg/L	Kanamycin	3μg/mL
Biotin	10mg/mL	tetracycline	3μg/mL
Mucus	500μg/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

5.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 ($9.75x10^2$ $TCID_{50}$/mL). No cross reactivity or interference was seen with the microorganisms listed in the table below.

Table 5: Microbial Interference Study Results

PPathogens	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 10^5 PFU/mL	Haemophilus influenzae	3.8 x 10^5 PFU/mL
Human Coronavirus NL63	1 x 10^5 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

REFERRENCE

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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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