Singclean®

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COVID-19 Test Kit

（Colloidal Gold Method）

INTENDED USE

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 test result. 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 immunochromatographic assay. The test uses COVID-19 (SARS-CoV-2) antibody (test line T) and goat anti-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 processed buffer containing the sample is added to the sample well, COVID-19 (SARS-CoV-2) 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 which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result.

The test contains an internal control (C band) which should exhibit a burgundy colored band of the 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 must be retested with another device.

MATERIALS SUPPLIED

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

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. 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.

WARNINGS AND PRECAUTIONS

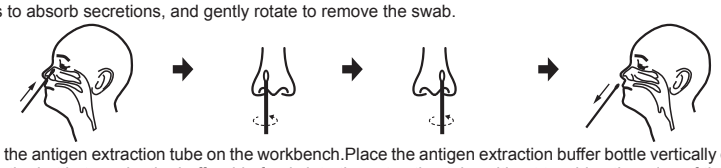
1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

SPECIMEN COLLECTION

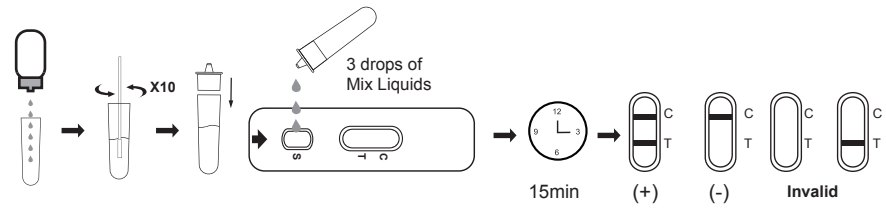
1. COVID-19 Test kit（Colloidal Gold Method）can be performed using nasal sampling.
2. Testing should be performed immediately after specimen collection.
3. Bring specimens to room temperature prior to testing.
4. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, and Antigen extract buffer control to equilibrate to room temperature (15-30°C) prior to testing.
1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
Operation procedure:
1. Ask the patient to remove the secretions on the surface of the anterior nasal cavity, keep the head slightly tilted, and gently and slowly insert the swab through the nasal cavity, it will reach the posterior nasal cavity, stay for a few seconds to absorb secretions, and gently 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 without touching 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 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 extraction tube and cap it tightly, and let it stand for about 1 minute.
6. Open the aluminum foil bag and take out the test card, add 3 drops (about 100ul) into the sample hole of the test card (or use a pipette to add 100ul), and start the timer.
7. Wait for the colored line to appear. 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 (SARS-CoV-2) antigen are detected in the specimen. The result is negative.
COVID-19 positive:
In addition to the presence of C band, if T band is developed, the test indicates for the presence of COVID-19 (SARS-CoV-2) 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 strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
3. A negative result for an individual subject indicates 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 result can occur if the quantity of the COVID-19 (SARS-CoV-2) antigen present in 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. 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. Accuracy

A total of 518 samples were tested in this study. The results of test reagent and control reagent both were 309 negative specimens and 209 positive specimens.

Method		RT-PCR		Total
		Positive	Negative	
COVID-19 Test Kit	Positive	206	3	209
	Negative	3	306	309
Total		209	309	518
Sensitivity		98.56 %	confidence interval	95.87 %~99.51 %
Specificity		99.03 %	confidence interval	97.18 %~99.67 %
Accuracy		98.84 %	confidence interval	97.50 %~99.47 %

2. Analytical Specificity

Cross Reactivity	Human coronavirus 229E, human coronavirus OC43, human coronavirus HKU1, human Coronavirus NL63, adenovirus (type 5), adenovirus(type 7), adenovirus (type 18), human metapneumovirus (hMPV), parainfluenza virus(type 1), influenza A virus, influenza B virus, Haemophilus influenza,rhinovirus(type 2), rhinovirus (type 14), rhinovirus (type 16), respiratory syncytial virus(type A-2), Streptococcus pneumoniae, and Streptococcus thermo, there is no crossover with this product.
Interfering Substances	2mg/mL hemoglobin, 2mg/mL mucin, 5mg/L human anti-mouse antibody (HAMA), 10mg/mL biotin, 500μg/mL mucus, 3μg/mL gentamicin, 120μg/mL cromolyn sodium, 60μg/mL oxymetazoline hydrochloride, 200μg/mL phenylephrine hydrochloride, 200μg/mL N-Acetaminophen, 3μg/mL aspirin, 3μg/mL ibuprofen, 3μg/mL morpholino hydrochloride, 3μg/mL cephalexin kanamycin, 3μg/mL tetracycline, 3μg/mL chloramphenicol, 3μg/mL erythromycin, 3μg/mL vancomycin, 3μg/mL nalidixic acid, 3μg/mL hydrocortisone Pine and 3μg/mL human insulin will not affect the test results.

3. Limit of Detection

Limit of detection	2ng/ml

REFERENCE

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2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013: 825-58.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24: 490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.

SYMBOLS USED ON PACKAGING NOTICE

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

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