CoVRFU-023

COVID-19 Antigen Rapid Test Device
（Colloidal Gold）Package Insert

IVD

Cat.:COV-201 **Specimens:** Nasal swabs

Version: 1.71 **Effective Date:** 2021-02 -18

Packing Specification: Single test/ box, 5 tests / box, 25 tests / box

INTENDED USE

The COVID-19 Antigen Rapid Test Device (Colloidal Gold) is a rapid visual immunoassay for the qualitative, presumptive detection of COVID-19 antigens from nasal swabs specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute COVID-19 virus infection.

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 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 Rapid Test Device (Colloidal Gold) detects COVID-19 antigens through visual interpretation of color development on the strip. COVID-19 antibodies are immobilized on the test region of the membrane respectively. During testing, the extracted specimen reacts with anti- COVID-19 antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient COVID-19 antigens in the specimen, colored band will form at the according test region of the membrane. The presence of a colored band in the test region indicates a positive result for the particular viral antigens, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

ABOUT MUTATED VIRUSES

Currently, these variants mainly affect the RBD fragment of the S protein, regardless of whether it is N501Y in the UK, 501Y.V2 in South Africa or B.1.617 in India. The constant fragment (N protein) used as the target fragment in the COVID-19 rapid antigen detector was not mutated.

KIT COMPONENTS

Individually packed Test Devices	Each test contains colored conjugates and reactive reagents precoated at the corresponding regions
Extraction solution	For specimens extraction
Extraction tubes	For specimen preparation
Nasal swabs	For specimen collection
Package insert	For operating instructions

MATERIALS REQUIRED BUT NOT PROVIDED

Timer For timing use

PRECAUTIONS

- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- The extraction solution contains a salt solution if the solution contacts the skin or eye, flush with copious amounts of water.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully before testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

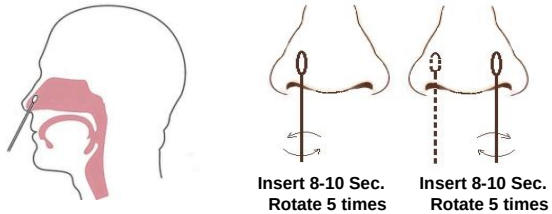
STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- **Specimen Collection**

For proper test performance, use the swabs supplied in the kit.
Nasal swab sample:
The nostrils must be moist. Do not touch the tip of the swab when removing it. Insert the swab 2-4cm into the nostril (1-2cm for children).
Note: Be careful not to insert too deep into the nostril to prevent internal soft tissue damage.
Rotate the swab at the nasal mucosa at least 5 times for about 8-10 seconds to ensure that enough mucus is absorbed by the swab. The same swab is then used to collect a sample from another nostril, it is important to obtain as much secretion as possible.



- **Specimen Transport and Storage:**

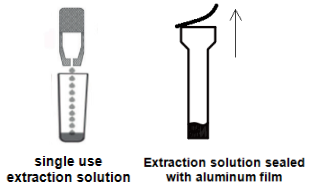
Specimens should be tested as soon as possible after collection. If transport of the samples is required, the following transport media are recommended and have been tested and shown not to interfere with the performance of the test: Hank' s BalanceMKd salt solution, M5 Media, or saline. Alternatively, samples may be stored refrigerated (2-8℃), or at room temperature(15-30℃), in a clean, dry, closed container for up to eight hours prior to testing.

PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.

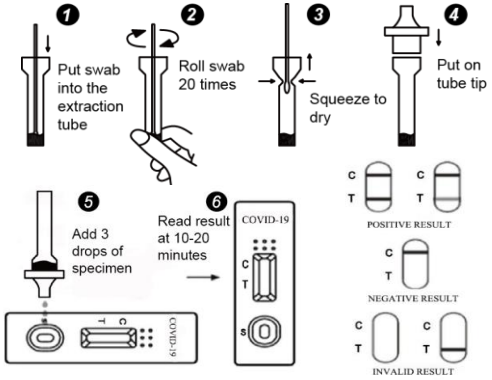
- **Prepare extraction solution:**

Single use extraction solution:
Open the bottle and add all the extraction solution into the extraction tube.
Extraction solution sealed with aluminum film:
Carefully remove the sealing film.



- **Specimen treatment:**

1. After the sampling, place the swab specimen into the tube.
2. Roll the swab at least 20 times while pressing the swab against the bottom and side of the extraction tube.
3. Roll the swab head against the inside of the Extraction Tube as you remove it. Try to release as much liquid as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
4. Put on the tube tip.
5. Add 3 drops of extracted sample into the sample well. Do not handle or move the Test Device until the test is complete and ready for reading.
6. As the test begins to work, color will migrate across the membrane. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

POSITIVE RESULT:A colored band appears in the control band region(C) and another colored band appears in the T band region
NEGATIVE RESULT: One colored band appears in the control band region (C). No band appears in the test band region (T)
INVALID RESULT: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:
1.The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2.Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

LIMITATIONS OF THE TEST

1. COVID-19 Antigen Rapid Test Device (Colloidal Gold) is for in vitro diagnostic use, and should only be used for the qualitative detection of COVID-19 antigen.
2. This test has been authorized only for the detection of proteins from COVID-19, not for any other viruses or pathogens.
3. The etiology of respiratory infection caused by microorganisms other than COVID-19 virus will not be established with this test. The COVID-19 antigen Rapid Test Device (Colloidal Gold) is capable of detecting both viable and non-viable COVID-19 particles. The performance of the COVID-19 antigen Rapid Test Device (Colloidal Gold) depends on antigen load and may not correlate with PCR performed on the same specimen.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of COVID-19 viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. The validity of COVID-19 Antigen Rapid Test Device (Colloidal Gold) has not been proven for identification or confirmation of PCR.
6. Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test result.
7. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.
8. Positive and negative predictive values are highly dependent on prevalence. False positive test results are more likely during periods of low COVID activity when prevalence is moderate to low.
9. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
10. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
11. Negative results, from patients with symptom onset beyond five days, should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
12. If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

PERFORMANCE CHARACTERISTICS

PCR	COVID-19 Antigen Rapid Test Device (Colloidal Gold)		
	Positive	Negative	TOTAL
Positive	159	4	163
Negative	0	479	479
TOTAL	159	483	642
Relative Sensitivity: 159/163	97.55% (95%CI: 93.84%~99.33%)		
Relative Specificity: 479/479	100% (95%CI: 99.38%~100%)		
Overall Agreement: 638/642	99.22% (95%CI: 98.19%~99.75%)		
*95% Confidence Interval			

Table: COVID-19 Antigen Rapid Test Device

（Colloidal Gold） vs. PCR Results

LIMIT OF DETECTION (LOD)

2019-nCoV Strain Tested	LYSUN Biotechnology product
Stock 2019-nCoV Concentration	4.6×10^5TCID50/mL

Dilution	1/100	1/500	1/1000	1/3000	1/5000
Concentration in Dilution tested (TCID50/ml)	4.6×10^3	9.2×10^2	4.6×10^2	1.53×10^2	9.2×10^1
Call rates of 18 replicates near cut-off	100（18/18）	100（18/18）	100（18/18）	100（18/18）	55.5（10/18）
Limit of Detection (LoD) per Virus Strain	1.53×10^2TCID50/ml				

ANALYTICAL SPECIFICITY AND CROSS-REACTIVITY

The COVID-19 Antigen Rapid Test Device (Colloidal Gold) was evaluated with a total of 47 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 10^7 and 10^9 org/mL. Viral isolates were evaluated at a concentration of at least 10^4–10^8 TCID50/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 TCID50/mL and 14 influenza virus. None of the organisms or viruses listed below gave a positive result in the COVID-19 antigen Rapid Test Device (Colloidal Gold).

Bacterial Panel:

Acinetobacter calcoaceticus
Neisseria gonorrhoeae
Pseudomonas aeruginosa
Streptococcus pneumoniae
Proteus vulgaris
Streptococcus sp. Gp. C
Mycobacterium tuberculosis
Bacteroides fragilis
Neisseria meningitidis
Staphylococcus aureus
Streptococcus sanguis
Streptococcus sp. Gp. B
Streptococcus sp. Gp. G
Mycoplasma orale

Viral Panel:

Human Adenovirus B
Human Adenovirus C
Adenovirus type 10
Adenovirus type 18
Human Coronavirus 229E
Human Coronavirus OC43
Human Coxsackievirus A9
Coxsackievirus B5
Human herpesvirus2
MERS-Coronaviurs
Human Rhinovirus 2
Human Rhinovirus 14
Human Rhinovirus 16
Measles
Coronavirus NL63
Mumps
Sendai virus
Parainfluenza virus 2
Parainfl uenza virus 3

Influenza Virus	Viral Type
Beijing/262/95	A
H1N1 Strain A/ New Caledonia/20/99 IVR	A
116 H1N1 Solomon Islands/03/06	A
H3N2 Strain A/ Shangdong/9/93	A
H3N2 Strain A/ Panama/2007/99	A
H3N2 Strain A/ Kiev/301/94	A
Respiratory Syncytial Virus (RSV)	A
Wisconsin/67/05	A
Brisbane/10/06	A
Panama	B
Lee	B
Hong Kong	B
Maryland	B
Stockholm	B

INTERFERING SUBSTANCES

Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the COVID-19 Antigen Rapid Test Device (Colloidal Gold) at the levels tested: whole blood (2%); three OTC mouthwashes (25%); three OTC throat drops (25%); three OTC nasal sprays (10%); 4-Acetamidophenol (10 mg/mL); Acetylsalicylic Acid (20 mg/mL); Chlorpheniramine (5 mg/mL); Dextromethorphan (10 mg/mL); Diphenhydramine (5 mg/mL); Ephedrine (20 mg/mL); Guaiacol glyceryl ether (20 mg/mL); Oxymetazoline (10 mg/mL); Phenylephrine (100 mg/mL); and Phenylpropanolamine (20 mg/mL).

INDEX OF SYMBOLS

	Caution		Keep away from sunlight
	Manufacturer	LOT	Lot number
	Consult instructions for use		Do not re-use
	Keep dry		Use-by date
REF	Catalogue number	IVD	In vitro diagnostic medical device
	Do not use if package is damaged	2℃ 30℃	Store between 2-30℃
CE	CE-mark	EC REP	Authorized representative in the European Community
	Date of manufacture	Σ	Contents sufficient for <n> tests

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