CE

Instructions For Use

PRODUCT NAME

COVID-19 Antigen Rapid Test Strip (Colloidal Gold Method)

SPECIFICATION

Product code	Specification
DV103-01	10 tests/kit
DV103-02	50 tests/kit
DV103-03	100 tests/kit

INTENDED USE

COVID-19 Antigen Rapid Test Strip (Colloidal Gold Method) is used for the qualitative detection of COVID-19 antigens in human nasal or throat swabs sample, as an early auxiliary diagnostic reagent for clinical patients infected with COVID-19, which is not used as a basis for the diagnosis and confirmation of novel coronavirus pneumonia.

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 Antigen Rapid Test Strip (Colloidal Gold Method) is a colloidal gold immune-chromatographic assay. It detects the nucleocapsid protein of COVID-19. The test uses COVID-19 (SARS-CoV-2) antibody (test line T) and goat anti-chicken IgY (control line C) immobilized on a nitrocellulose membrane. The burgundy colored conjugate pad contains colloidal gold conjugated to another COVID-19 (SARS-CoV-2) antibody conjugated with colloid gold and chicken IgY-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 conjugated 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 line), 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 test result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immune-complex goat anti-chicken IgY/chicken IgY-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.

PRODUCT CONTENTS

Content	**Specification**	**Storage**
Test Cassette	10 tests/kit; 50 tests/kit; 100 tests/kit	4~30°C
Sample Diluent	0.5 ml/tube; 10 tubes/kit; 50 tubes tests/kit; 100 tubes /kit.	4~30°C
Sterilized Swab	10 pcs/kit; 50 pcs/kit; 100 pcs/kit.	4~30°C
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Note: A Timer is necessary for testing but which was not supplied in the kit.

Storage conditions and validity

1. Store the product in a dry and cool place under the condition of 4~30°C, avoid direct sunlight, and do not freeze. The shelf life is 12 months. After the packages of test cassette and sample diluent are opened, such test cassette and sample diluent should be used within 1 hour as soon as possible if the humidity is lower than 65% and used immediately if the humidity is greater than 65%.
2. After opening the packaging of the cassette and sample collection tube, if the humidity is less than 65%, it should be used as soon as possible within 1 hour. If the humidity is above 65%, it should be used immediately.
3. See the date of manufacture and shelf life printed on the product label.

TEST PROCEDURE

1. Samples Collection

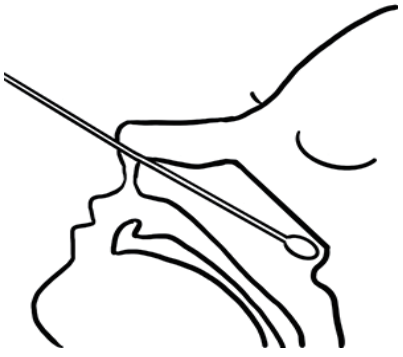
Nasal swab collection

Insert the swab into one nostril of the people were tested. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Take at least 15 seconds to collect the specimen. Using the same swab, and repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

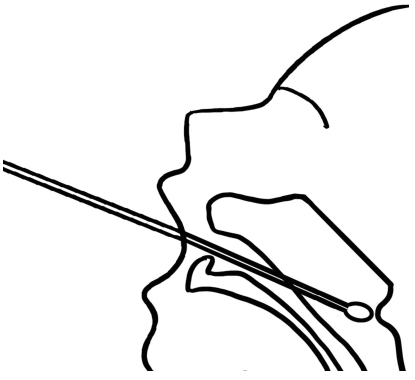
Withdraw the swab from the nasal cavity. The sample is now ready for processing using the COVID-19 test cassette. Insert the swab into a sample diluent tube and proceed to the following steps.

Throat swab collection

Sweep a swab across the mucus membranes of the posterior oropharynx in the region of the pharyngopalatine arch. Make sure the swab touches both sides of the throat. Withdraw the swab from the oral cavity. The sample is now ready for processing using the COVID-19 test cassette. Insert the swab into a sample diluent tube and proceed to the following steps.



Nasal swab sample collection



Throat swab sample collection

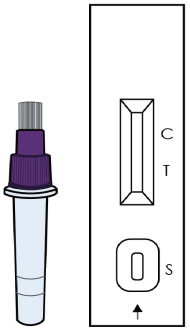
2. Test Method

Step 1. Remove one sample diluent tube and one COVID-19 test cassette from its foil pouch immediately before testing.

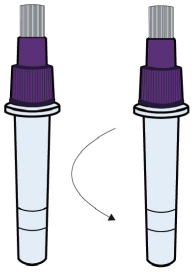
If left uncovered, debris may land on the device read window and interfere with line interpretation causing false positive, false negative or invalid results.

• Label one test cassette and one sample diluent tube for each specimen to be tested.

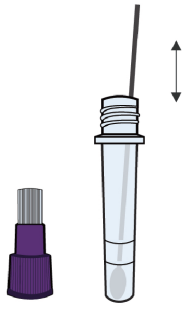
• Place the labeled sample diluent tube(s) in a rack in the designated area of the workspace.



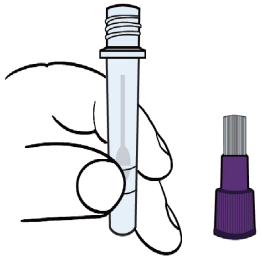
Step 2. Remove the purple cap from the sample diluent tube.



Step 3. Taking care not to splash contents out of the tube, insert the nasal or throat swab into the tube and plunge the swab up and down in the fluid for a minimum of 15 seconds.



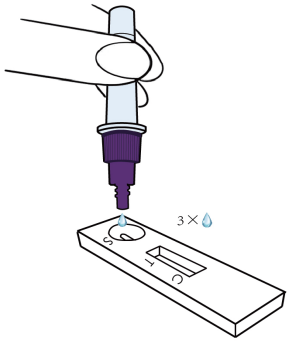
Step 4. Firmly squeeze the sides of the tube to extract the specimen from the head of the swab. For nasal swab, remove it from the sample diluent and discard. For throat swab, snap it off along the mark and seal it into the sample diluent tube.



Step 5. Screw the purple cap firmly onto the sample diluent tube containing the processed sample. Mix thoroughly by swirling or flicking the bottom of the tube then remove the drop cap (white cap).

Step 6. Adding the specimen to the test cassette.

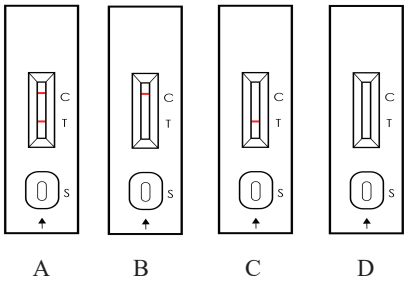
- Invert the sample diluent tube and hold it vertically (approximately one inch above the sample well).
- Gently squeeze the ridged body of the tube, dispensing three drops of the processed specimen into the sample well.
- Excess volume remains for retesting if necessary.



Step 7. After adding the sample, allow the test to run for 10minutes but no longer than15 min.

RESULT INTERPRETATION

1. A positive specimen will give two pink/purple colored lines. This means the people can be infected with the COVID-19.
2. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line is positive (A).
3. A negative specimen will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected (B). If no line develops or just T line develops, the assay is invalid. Invalid tests should be repeated (C/D).



LIMITATIONS

1. The test results of this product are interpreted visually and are susceptible to visual error or subjective judgment. Therefore, it is recommended to retest when the band color cannot be clearly identified.
2. The test accuracy depends on the sample collection process. Improper sample collection, improper sample storage, stale sample or repeated freezing and thawing will affect the test results.
3. The presence of individual drugs such as high concentrations of over-the-counter and prescription drugs (nasal sprays) in the samples collected can interfere with the results. If the results are suspicious, retest is necessary.
4. The test results of this kit are for clinical reference only, and should not be used as the sole basis for clinical diagnosis. For the clinical management of patients, their symptoms/signs, medical history, other laboratory tests, and treatment responses should be comprehensively considered.
5. This kit is for qualitative detection and cannot be used to determine the antigen content.
6. Due to the methodological limitations of the antigen test reagent, the analysis sensitivity is generally lower than that of the nucleic acid reagent. Therefore, the experiment operators should pay more attention to the negative results and make a comprehensive judgment based on other test results. It is suggested that the negative results in question should be checked by nucleic acid test or virus culture identification method.
7. Analysis of the possibility of false negative results: ① Improper sample collection, transport and handling and too low virus titer in samples may lead to false negative results; ② genetic variation of the virus may lead to changes in antigenic determinants, resulting in false negative results; ③ the optimal sample type and the optimal sampling time after infection (peak virus titer) have not been verified. Therefore, taking samples from the same patient at different time and multiple sites may avoid false negative results.

PRODUCT PERFORMANCE INDEX

1. Cross Reactivity

   The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of the reagent, and there is no cross-reaction.

Potential Microbial Interference	Concentration Tested	Cross-Reactivity(Yes/NO)
Endemic human coronavirusNL63	≤9.87×10^3 PFU/mL	NO
MERS coronavirus	≤793PFU/mL	NO
Influenza A virus（H3N2）	≤8.82×10^4 PFU/mL	NO
Influenza B virus（Malaysia）	≤2.92×10^4 PFU/mL	NO
Rhinovirus	≤4.17×105 PFU/mL	NO
Endemic human coronavirus OC43	≤ 1.0×10^5 PFU/mL	NO
Endemic human coronavirus 229E	≤ 1.0×10^5 PFU/mL	NO
Adenovirus	≤ 1.0×10^5 PFU/mL	NO
Metapneumovirus	≤ 1.0×10^5 PFU/mL	NO
Parainfluenza virus type 1	≤ 1.0×10^5 PFU/mL	NO
Parainfluenza virus type 2	≤ 1.0×10^5 PFU/mL	NO
Parainfluenza virus type 3	≤ 1.0×10^5 PFU/mL	NO
Parainfluenza virus type 4	≤ 1.0×10^5 PFU/mL	NO
Influenza A virus (H1N1)	≤ 1.0×10^5 PFU/mL	NO
Enterovirus	≤ 1.0×10^5 PFU/mL	NO
Respiratory syncytial virus	≤ 1.0×10^5 PFU/mL	NO
Haemophilus influenzae	≤1.0×10^6 CFU/mL	NO
Streptococcus pneumoniae	≤1.0×10^6 CFU/mL	NO
Streptococcus pyogenes	≤1.0×10^6 CFU/mL	NO
Candida albicans	≤1.0×10^6 CFU/mL	NO
Bordetella parapertussis	≤1.0×10^6 CFU/mL	NO
Mycoplasma pneumoniae	≤1.0×10^6 CFU/mL	NO
Chlamydia pneumoniae	≤1.0×10^6 CFU/mL	NO
Legionella pneumophila	≤1.0×10^6 CFU/mL	NO
Mycobacterium tuberculosis	≤1.0×10^6 CFU/mL	NO
Pneumocystis yersinensis	≤1.0×10^6 CFU/mL	NO
Pseudomonas aeruginosa	≤1.0×10^6 CFU/mL	NO

Staphylococcus aureus	≤1.0×10^6 CFU/mL	NO
Streptococcus salivarius	≤1.0×10^6 CFU/mL	NO
Endemic human coronavirus HKU1	≤1 × 10^5 PFU/mL	NO
SARS coronavirus	≤1 × 10^5 PFU/mL	NO
Staphylococcus salivarius	≤1 × 10^6 CFU/mL	NO

Note: 1TCID$_{50}$/mL≈0.7CFU/mL

Based on the data generated by this study, the substances tested COVID-19 Antigen Rapid Test Strip (Colloidal Gold Method) do not cross-react.

2. Endogenous Interfering Substances

A study was performed to demonstrate that 32 potentially interfering substances that may be found in the upper respiratory tract do not cross-react or interfere with the negative and positive test results of the reagent, and there is no cross-reaction.

Substance	**Concentration**	**Cross-Reactive Results**
Mucin	0.50%	Negative
Guaiacol glyceryl ether	1 μg/mL	Negative
Arbidol Hydrochloride Hydrate	1 mg/mL	Negative
Zanamivir	2 mg/mL	Negative
Meropenem	1 mg/mL	Negative
Oseltamivir	3 mg/mL	Negative
Ritonavir	1 mg/mL	Negative
Histamine hydrochloride	3 mg/mL	Negative
levofloxacin	1 mg/mL	Negative
Oxymetazolin hydrochloride	1 mg/mL	Negative
Ceftriaxone sodium	1 mg/mL	Negative
Cefradine	100 mg/mL	Negative
Cefalexin	100 mg/mL	Negative
Benzocaine	5 mg/mL	Negative
Tobramycin	2 mg/mL	Negative
Lopinavir	1 mg/mL	Negative
Azithromycin	3 mg/mL	Negative
Watermelon frost buccal tablets	100 mg/mL	Negative
Dexamethasone	0.5 mg/mL	Negative
Flunisolide	2 mg/mL	Negative
Beclomethasone	10 mg/mL	Negative
Alpha-interferon	1 mg/mL	Negative
Phenylephrine hydrochloride	5 mg/mL	Negative
Acetaminophen	10 mg/mL	Negative
Ibuprofen	1 mg/mL	Negative
Aspirin	5 mg/mL	Negative
Acetylsalicylic acid	5 mg/mL	Negative
Hydrocortisone	1 mg/mL	Negative
Albuterol	1 mg/mL	Negative
Chlorpheniramine	5 mg/mL	Negative
Diphenhydramine	5 mg/mL	Negative
Budesonide	10 mg/mL	Negative
Mometasone	1 mg/mL	Negative
Fluticasone	1 mg/mL	Negative
NeilMed	5 mg/mL	Negative
Menthol	0.15 mg/mL	Negative
Quinine (malaria)	150 μM	Negative
Lamivudine (retroviral drug)	1 mg/mL	Negative
Biotin	0.1 mg/mL	Negative
HAMA	600 ng/mL	Negative

3. Clinical Performance

The COVID-19 Antigen Rapid Test Strip (Colloidal Gold Method) has been evaluated to study product performance. A commercialized molecular assay was used as the reference method. The study included 527 samples (167 confirmed positive and 360 negative samples)

Method		**PCR Test**		**Subtotal**
COVID-19 Antigen Rapid Test Strip (Colloidal Gold Method)	Results	Positive	Negative	
	Positive	161	0	161
	Negative	6	360	366
Total		167	360	527
Relative Sensitivity:161/167		96.41% (95%CI*: 92.40%~98.30)		
Relative Specificity: 360/360		100% (95%CI*: 98.90%~100%)		
Accuracy: 521/527		98.86% (95%CI*: 97.53%~99.47%)		

4. Minimum LoD: the minimum LoD of the kit should not be higher than 1ng/mL.
5. Repeatability: Intra-lot repeatability: test 2 repeatability enterprise references (R1-R2) in duplicate respectively, and the results should all be positive and the color development should be uniform; inter-lot repeatability: use three consecutive lots of kits to test the repeatability enterprise references. Perform the testing in quintuplicate for each concentration by each lot of kits. The results should all be positive and the color development should be uniform.
6. High Dose Hook Effect

No high dose hook effect was observed when testing heat inactivated SARS-CoV-2 virus.

PRECAUTIONS

1. The positive results obtained by this kit should be further confirmed using other methods.
2. The kit should be sealed and stored to prevent moisture which may affect the test results.
3. The depth of the color of the test line is not necessarily related to the concentration of the antigen in the sample, and the result interpreted after 15min is invalid.
4. When receiving, sorting and centrifuging specimens from general patients, feverish patients and suspected patients, the operators must have Level-II biosafety protection. In special circumstances (such as suspected spills), the protection should be upgraded to Level-III biosafety protection. When receiving, sorting and centrifuging specimens from confirmed cases, the samplers must have Level-III biosafety protection.
5. Receiving and handling of specimens in the laboratory should be provided with Level-III biosafety protection and manual test items should be conducted in the biosafety cabinet.
6. Components of the kit and wastes after testing should be disposed of as infectious pollutants.

REFERENCES

[1] WHO Technical Guidance on COVID-19 (First Chinese translation).

[2] Key Points for Technical Review of 2019-nCoV Antigen/Antibody Test Reagent Registration (Trial), Center for Medical Device Evaluation of the National Medical Products Administration, 2019.

[3] Guidelines for the Diagnosis and Treatment of Novel Coronavirus-infected Pneumonia (Trial Version 6), release date: 2020-02-03.

APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION FOR USE

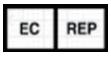
Approval Date: 2021.11.15

Revision Date: 2021.11.01

Date of Issue: 2021.11.17

Version: V1.1

SYMBOLS AND INTERPRETATIONS

				
For in Vitro Diagnostic Use Only	Attention, See Instruction for Use	Do Not Use if Package is Damaged	Temperature Limitation	Do Not Reuse
				
Afraid of the Sun	Manufacturer	Date of Production	Validity	Batch Code
				
Conformity of European	Authorized Representative	Tests Per Kit	Keep Dry	Catalog Number

BASIC INFORMATION

Registrant/manufacturer name: TransGen Biotech Co., Ltd.
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