COVID-19 Antigen Test Kit (Colloidal Gold)

【CATALOG NO. AND PACKING SPECIFICATION 】

Catalog NO.	Packing Specification
VC2001C	1 Test/Kit
VC2002C	5 Tests/Kit
VC2003C	25 Tests/Kit

【INTENDED USE】

The COVID-19 Antigen Test Kit is used for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human throat swab, nasopharyngeal swab or nasal swab samples from individuals suspected of COVID-19 by their healthcare provider within the first ten days of SARS-CoV-2 infections. O**nly for in vitro diagnostic use.**

The COVID-19 Antigen Test Kit is intended for use by healthcare professionals or trained operators who are proficient in performing rapid tests and trained clinical laboratory personnel specifically instructed on in vitro diagnostic procedures and proper infection control procedures or individuals similarly trained in point of care settings.

【SUMMARY AND EXPLANATION】

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.

Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

【PRINCIPLE OF THE TEST】

This kit is based on the principle of highly specific antibody-antigen reaction and colloidal gold labeling immunochromatographic analysis technology. The reagent contains COVID-19 monoclonal antibody prefixed in the test area (T) on the membrane and the COVID-19 monoclonal antibody coated on the label pad-colloidal gold mixture. The sample is dripped into the sample well and reacts with the COVID-19 monoclonal antibody which is bound to the pre-coated colloidal gold particles when testing. Then the mixture is chromatographed upwards with capillary effects. If it is positive, the antibody labeled by colloidal gold particles will first bind to the COVID-19 virus Ag in the sample during chromatography. Then the conjugates are bound by the COVID-19 monoclonal antibody fixed on the membrane, and a red line appears in the test area (T). If it is negative, there's no red line in the test area (T). Whether the sample contains COVID-19 antigen or not, a red line will appear in the quality control area (C). The red line appearing in the quality control area (C) is the standard for judging whether there are enough samples and whether the chromatographic process is normal, and it also serves as the internal control standard for the reagent.

【MAIN COMPONENTS】

1. COVID-19 Ag cassettes: 1/5/25 Tests
2. Extraction Buffer: 1 bottle (1pc/box, 1ml/bottle), 1 bottle (5pcs/box, 3ml/bottle), 2 bottles (25pcs/box, 7ml/bottle)
3. 1/5/25 Extraction tube(s) and dropper tip(s)
4. 1/5/25 Swab(s)
5. 1 Package Insert

【MATERIAL REQUIRED BUT NOT PROVIDED】

Clock or Timer

【WARNINGS AND PRECAUTIONS】

1. This product is a single-use in vitro diagnostic reagent. Do not reuse it. Do not use it if it is

expired.
2. Testing should only be performed using the swab and Extraction solution provided in the kit. Do not interchange components from different kit lots.
3. The positive result obtained by using this kit needs further confirmation by other methods.
4. The test cassette stored at low temperature should be equilibrated to room temperature before opening to avoid moisture absorption.
5. The intensity 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 15 minutes is invalid.
6. Specimens must be processed as indicated in **PRIMARY SAMPLE COLLECTION, HANDING AND STORAGE** sections of this Product Insert. Failure to follow the instructions for use can result in inaccurate results. It is recommended to use fresh samples, do not use repeatedly freeze-thaw samples.
7. Inadequate or inappropriate specimen collection and storage can adversely affect the results.
8. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used COVID-19 Ag cassettes and used extraction buff vials maybe potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulatory requirements.
9. Dispose of test device and materials as biologically hazardous waste in accordance with federal, state, and local requirements.
10. For clinical reference only, and cannot be used as a basis for confirming or excluding cases alone.

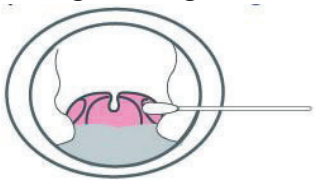
【STORAGE AND STABILITY】

1. Store at 2℃ to 35℃ in the sealed pouch up to the expiration date (24 months).
2. Keep away from sunlight, moisture and heat.
3. DO NOT FREEZE.
4. When the humidity is below 60%, use it within 1 hour after opening. When the humidity is above 60%, use it immediately after opening. Production date, expiry date will be in the label.

【PRIMARY SAMPLE COLLECTION,HANDING AND STORAGE】

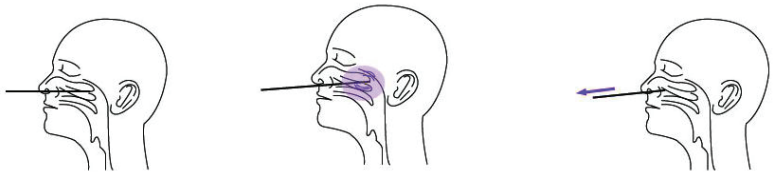
1. Throat secretions collection:

a) Insert the swab provided in the kit completely from the mouth into the throat, centering on the red part of the throat wall and maxillary tonsils.
b) Rub the bilateral throat tonsils and throat wall moderately.
c) Avoid touching the tongue and remove the swab.



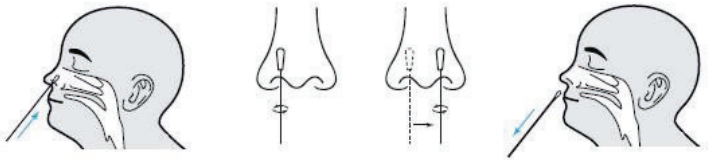
2. Nasopharyngeal secretions collection

a) Carefully insert the swab provided in the kit into the nostril of the patient, reaching the surface of posterior nasopharynx that presents the most secretion under visual inspection.
b) Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
c) Withdraw the swab from the nasal cavity.



3. Nasal secretions collection

a) Insert the swab provided in the kit into one nostril of the patient. The swab tip should be inserted up to 2～4cm until resistance is met.
b) Roll the swab 5times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
c) Using the same swab, repeat this process for the other nostril to ensure that adequate sample is collected from both nasal cavities.
d) Withdraw the swab from the nasal cavity.



The samples should be treated with the sample extraction solution provided with this kit as soon as possible after collection. The collected extracts should be detected within 2 days or stored at 2-8 ℃ after sealing and detected within 4 days.

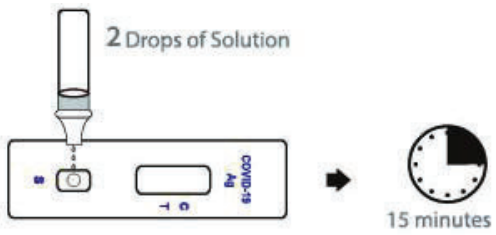
【TEST PROCEDURE】

1. Specimen extraction

a) Add 0.5mL (about 10 drops) of the sample extraction buffer into the extraction tube.
b) Insert the swab into the extraction tube which contains 0.5mL of the extraction buffer. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
c) Leave the swab in the extraction tube for 1 minute.
d) Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.
e) Fit the dropper tip with filter on top of the extraction tube tightly.

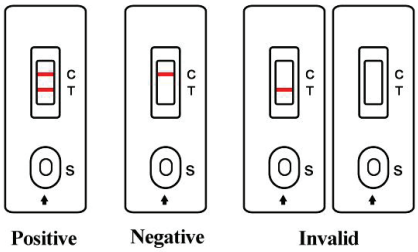
2. Detection operations:

a) Open a pouch containing a test cassette. Place the test cassette on a dry, horizontal work surface.
b) Add 2 drops (about 60μl) of sample solution extract to the sample well of the test cassette.
c) Observe the results showed within 10-15 minutes, and the results showed after 15 minutes have no clinical significance.



【INTERPRETATION OF RESULTS】

Negative : Only a red line appears in the quality control area (C), and no line appears in the test area (T).
Positive : Two red lines appear. One is in the test area (T) and the other is in the quality control area (C).
Invalid : No red line displays in the quality control area (C). This indicates that the incorrect operation or the test cassette has deteriorated or damaged. Repeat the test with a new kit. If the problem persists, stop using this lot number immediately and contact your local supplier.



Note: Invalid samples should be treated as infectious pollutants, and samples should be collected again.

【LIMITATIONS】

1. This kit is only for the detection of respiratory secretions from throat swabs, nasopharyngeal swabs or nasal swabs.
2. The accuracy of the test depends on the sample collection , handing ,storage and operation procedure. Improper sample collection, improper storage of samples, stale samples, or repeated freeze-thaw cycles of samples will affect the test results.
3. The presence of individual drugs in the sample collected, such as high concentrations of over-the-counter drugs and prescription drugs (nasal sprays), can interfere with the results. If the results are suspicious, please retest.
4. The test cassette only provides qualitative detection of the SARS-COV-2 in the sample. If you need to detect the specific content of an indicator, please use the relevant professional instruments.
5. The test result of this kit is for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment responses.
6. Due to the limitation of the method of antigen detection reagents, its analytical sensitivity is generally lower than that of nucleic acid reagent reagents. Therefore, the experimenters should pay more attention to the negative results and need to make a comprehensive judgment in combination with other test results. It is recommended to review the suspicious negative results by using nucleic acid detection or virus culture identification methods.
7. Analysis of the possibility of false negative results:
①Unreasonable sample collection, transportation and processing, and too low concentration of tested substances in samples may lead to false negative results.
②Genetic variations of virus can cause changes in antigenic determinants, which can lead to false negative results. This is more likely to occur by using monoclonal antibody reagents.
③The optimal sample type and sampling time (peak virus titer) after infection have not been verified, so collecting samples fractionally, in multiple parts on the same patient may avoid false negative results.

【PERFORMANCE CHARACTERISTICS】

1. Clinical Sensitivity, Specificity and Accuracy

A total of 319 fresh throat swab samples were collected and tested, which includes 107 positive samples from COVID-19 infected patients within the first 7 days and 212 negative samples. The nasopharyngeal swabs were also collected from these 319 volunteers and tested. The COVID-19 Antigen Test Cassette results were compared to the results of SFDA authorized RT-PCR assays for Novel Coronavirus (2019-nCoV) in throat swabs. Overall study results are shown in Table 1and Table 2.

Table 1: COVID-19 Antigen Test Cassette(nasopharyngeal) VS RT-PCR

Assessment reagents	Nucleic acid test (RT-PCR)		
	Positive	Negative	Total
Positive	105	2	107
Negative	2	210	212
Total	107	212	319

Relative Sensitivity: 98.13 %(95%CI:93.44%-99.49%)
Relative Specificity: 99.06 %(95%CI:96.63%-99.74%)
Accuracy: 98.75 %(95%CI:96.82%-99.51%)

Table 2: COVID-19 Antigen Test Cassette (throat) VS RT-PCR

Assessment reagents	Nucleic acid test (RT-PCR)		
	Positive	Negative	Total
Positive	104	3	107
Negative	3	209	212
Total	107	212	319

Relative Sensitivity: 97.20% (95 %CI: 92.02%-99.42%)
Relative Specificity: 98.58 %(95%CI: 95.92%-99.71%)
Accuracy: 98.12% (95%CI: 95.95%-99.31%)

A total of 403 fresh nasal swab samples were collected and tested, which includes 134 positive samples from COVID-19 infected patients within the first 7 days and 269 negative samples. The COVID-19 Antigen Test Cassette results were compared to the results of SFDA authorized RT-PCR assays for Novel Coronavirus (2019-nCoV) in throat swabs. Overall study results are shown in Table 3.

Table 3: COVID-19 Antigen Test Cassette (nasal) VS RT-PCR

Assessment reagents	Nucleic acid test (RT-PCR)		
	Positive	Negative	Total
Positive	130	2	132
Negative	4	267	271
Total	134	269	403

Relative Sensitivity: 97.01 %(95%CI:92.53%-99.18%)
Relative Specificity: 99.26%(95%CI:97.34%-99.91%)
Accuracy: 98.51 %(95%CI:96.97%-99.45%)

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 4.8×10^5 $TCID_{50}$/mL, was spiked into negative specimen and serially diluted. Each dilution was ran in triplicate on the COVID-19 Antigen Test Cassette. The Limit of Detection of the COVID-19 Antigen Test is 1.2×10^2 $TCID_{50}$/mL.

3.High Dose Hook Effect

No high dose hook effect was observed when testing up to a concentration of 4.8×10^5 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus.

4.Cross Reactivity

Samples positive for the following organisms were found negative when tested with the COVID-19 Antigen Test Cassette

Pathogens	Concentration
Human coronavirus HKU1	2.0×10^6 $TCID_{50}$/mL
Human coronavirus OC43	2.0×10^6 $TCID_{50}$/mL
Human coronavirus NL63	2.0×10^6 $TCID_{50}$/mL
Human coronavirus 229E	2.0×10^6 $TCID_{50}$/mL
MERS- coronavirus	1.0×10^6 $TCID_{50}$/mL
Respiratory syncytial virus	2.0×10^6 $TCID_{50}$/mL
Influenza A virus(H3N2)	1.0×10^5 PFU/mL
Influenza A virus(H1N1)	1.0×10^5 PFU/mL
Influenza B virus(Yamagata)	1.0×10^5 PFU /mL
Influenza B virus(Victoria)	1.0×10^6 PFU /mL
Parainfluenza virus type II	1.0×10^6 PFU /mL
Rhinovirus	2.0×10^6 $TCID_{50}$/mL
Adeno virus	2.0×10^6 $TCID_{50}$/mL
Enterovirus EV71	2.0×10^6 $TCID_{50}$/mL
Measles virus	2.0×10^6 $TCID_{50}$/mL
Mumps virus	1.0×10^6 PFU /mL
Mycoplasma pneumonia	1.2×10^6 CFU /mL
Chlamydia pneumonia	2.0×10^6 IFU /mL
Mycobacterium tuberculosis	2.0×10^6 CFU /mL
Streptococcus pneumoniae	3.6×10^6 CFU /mL
Varicella-zoster virus	2.0×10^6 $TCID_{50}$/mL
Human cytomegalovirus	2.0×10^6 $TCID_{50}$/mL
Staphylococcus aureus	3.2×10^8CFU /mL

5.Interfering Substance

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity, throat or nasopharynx, were evaluated with the COVID-19 Antigen Test Kit at the concentrations listed below and were found not to affect test performance.

Substance	Concentration
Human blood(EDTA anticoagulated)	20%(v/v)
Mucin	2mg/mL
Ribavirin	5mg/mL
Levofloxacin	5mg/mL
Tobramycin	5μg/mL
Meropenem	5mg/mL
Arbidol	5mg/mL
Oseltamivir phosphate	5mg/mL
Triamcinolone	10mg/mL
Azithromycin	5 mg/mL
menthol	10mg/mL
Hexadecadrol	20%(v/v)
0.9% sodium chloride	20%(v/v)
Oxymetazolin	15%(v/v)
Phenylephrine	15%(v/v)
Fluticasone	20%(v/v)
Fluticasone propionate	20%(v/v)
Flunisolide	20%(v/v)
Budesonide	20%(v/v)
Mometasone	20%(v/v)

【LITERATURE REFERENCES】

[1] Zheng Yuan,Shang Jian,Yang Yang,Liu Chang,Wan Yushun,Geng Qibin,Wang Michelle,Baric Ralph,Li Fang. Lysosomal Proteases Are a Determinant of CoronavirusTropism.[J].Journalofvirology,2018,92(24).

[2] Liya Ye,Xiaoling Wu,Liguang Xu,Qiankun Zheng,Hua Kuang. Preparation of an anti-thiamethoxam monoclonal antibody for development of an indirect competitive enzyme-linked immunosorbent assay and a colloidal gold immunoassay[J].Food and Agricultural Immunology,2018,29(1).

INDEX OF SYMBOLS

Symbol	Introductions	Symbol	Introductions	Symbol	Introductions
LOT	Batch Code		Do not reuse" are "single use, "Use only once	CE	CE Symbol
	Warnings and Precautions	NON STERILE	non-sterile		Symbol for " USE BY"
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE		Manufacture Date		CONSULT INSTRUCTIONS FOR USE
	Manufacturer Name Address	EC REP	Name and Address of European Union Representative	2℃ 35℃	Temperature Limitation (2-35℃)

Tianjin Vancoein Biotechnology Co.,Ltd.
Add: East side of the second floor of Building No. 29—A, Innovation and Pioneer Park, No. 4668, Xinbei Road, Tanggu Ocean Science and Technology Park, Tianjin Binhai High-tech Zone—2
Tel: 86-022-25215161