CE

COVID-19 Antigen Test Kit (Colloidal Gold) (Cassette)

For professional in vitro diagnostic use only

Please read all the information in the leaflet before performing the test.

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 and nasal swab samples from individuals suspected of COVID-19, only for in vitro diagnostic use.

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

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 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.

COMPONENTS

Components of the test strip in the cassette:

Sample pad: contains buffered salts and detergents.

Label pad: contains gold-labeled mouse anti-COVID-19 monoclonal antibody.

Nitrocellulose membrane:

Control area: contains Goat anti-mouse IgG polyclonal antibody and buffer.

Test area: contains mouse anti-COVID-19 monoclonal antibody and buffer.

Absorbent pad: made of highly absorbent paper.

MATERIALS SUPPLIED

1. One pouch contains a test cassette and a desiccant. The desiccant is for storage purposes only and is not used in the test procedures.
2. Sample extraction buffer: 1 bottle (1pc/box), 1 bottle (5pcs/box),2 bottles (20pcs/box), 2 bottles (25pcs/box)
3. 1/5/20/25 Extraction tube(s) and dropper tip(s)
4. 1/5/20/25 Swab(s)
5. 1 Work Station
6. 1 Package Insert.

MATERIAL REQUIRED BUT NOT PROVIDED

1. 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. Please use the swab and sample extraction solution provided in this kit when sampling. Each component of the kit cannot be used in batches.
3. The positive result obtained by using this kit needs further confirmation by other methods.
4. The temperature of the experimental environment should be avoided. The reaction temperature should be 10~30℃, and the reaction humidity should be less than 60%. 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. It is recommended to use fresh samples, do not use repeatedly freeze-thaw samples.
7. The components of the kit and the waste produced by the test are treated as infectious pollutants.
8. For clinical reference only, and cannot be used as a basis for confirming or excluding cases alone.

STORAGE AND SHELF LIFE AFTER FIRST OPENING

1. Store at 2℃ to 30℃ 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

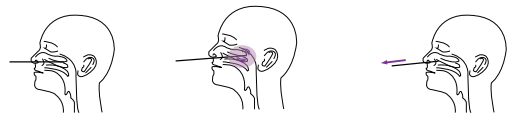
Use the nasopharyngeal swab supplied in the kit.

1. Nasal secretions collection

(1)Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx. that presents the most secretion under visual inspection.

(2)Swab over the surface of the posterior nasopharynx. Rotate the swab several times.

(3)Withdraw the swab from the nasal cavity.

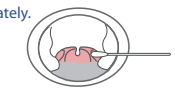


2. Throat secretions collection:

(1)Insert the swab completely from the mouth into the throat, centering on the red part of the throat wall and maxillary tonsils.

(2)Rub the bilateral throat tonsils and throat wall moderately.

(3)Avoid touching the tongue and remove the swab.



The samples should be treated with the virus sampling solution or the sample extraction solution provided with this kit as soon as possible after collection. And complete the test in 5 minutes.

TEST PROCEDURE

1. Specimen extraction

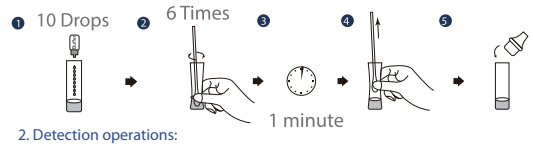
(1)Add 0.5mL (about 10 drops) of the sample extraction buffer into the extraction tube.

(2)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.

(3)Leave the swab in the extraction tube for 1 minute.

(4)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.

(5)Fit the dropper tip with filter on top of the extraction tube tightly.

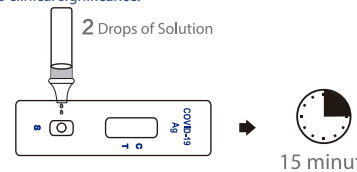


2. Detection operations:

(1)Open a pouch containing a test cassette. Place the test cassette on a dry, horizontal work surface.

(2)Add 2 drops (about 60μl) of sample solution extract to the sample well of the test cassette.

(3)Observe the results showed within 10-15 minutes, and the results showed after 15 minutes have no clinical significance.

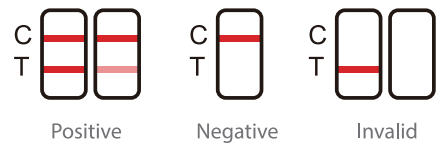


INTERPRETATION OF RESULTS

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.

CONTROL PROCEDURE

The test kit has its own built-in quality control indicator. After performing the test and no line in the Control area (C) of the reaction membrane is visible, the sample has not been added correctly or the test may have deteriorated.

LIMITATIONS

1. This kit is only for the detection of respiratory secretions from nasopharyngeal swabs and oropharyngeal swabs.
2. The accuracy of the test depends on the sample collection , handing ,storage and operation procedure. Improper sample collection, improper storage of samples, unfresh 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 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

● Analysis of Sensitivity and Specificity
Detection of 3 COVID-19 antigen sensitivity reference products (S1, S2, S3), and the result is positive for S1; positive or negative for S2; negative for S3.
Detection of 5 COVID-19 antigen positive corporate reference products, and the results were all positive.
Detection of 5 COVID-19 antigen negative corporate reference products, and the results were negative.
COVID-19 Antigen Test Kit (Colloidal Gold) showed no cross reaction with followed positive samples : Endemic human coronavirus (HKU1,OC43,NL63,229E), influenza A virus, influenza B virus, respiratory syncytial virus, rhinovirus, adenovirus, enterovirus, EB Virus, Measles virus, human cytomegalovirus, Rotavirus, Norovirus, Mumps virus, varicella-zoster virus, parainfluenza virus type II, Mycoplasma pneumoniae, and not less than 100 health swab specimens.
● Repeatability and Reproducibility
Tests showed positive results with all positive samples and showed negative results with negative samples. There was no significant difference observed to the same sample when repeatedly testing 10 tests in the same batch. No appreciable intra and inter lot variation were observed among different tests for each lot, different lots, different operators at different test sites in different time for the same sample.
The results demonstrated that the repeatability and reproducibility of COVID-19 Antigen Test kit are satisfactory.
● Diagnostic Sensitivity and Specificity
246 samples were collected from selected subjects, total 105 throat/nasal swab samples from COVID-19 infected patients and 141 non-COVID-19 infected throat/nasal swab samples were tested. All samples were confirmed by nucleic acid test (RT-PCR).-Calculated the specificity and sensitivity, the results are as follows:

Assessment reagents	Nucleic acid test (RT-PCR)		
	Positive	Negative	Total
Positive	103	0	103
Negative	2	141	143
Total	105	141	246

Diagnostic Sensitivity: 103/(103+2)×100%=98.10%
Diagnostic Specificity: 141/(0+141)×100%=100.00%
Overall coincidence rate: (103+141)/ (103+0+2+141)×100%=99.19%

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

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

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