COVID-19

COVID-19 Antigen Saliva 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 Saliva Test Kit is used for the qualitative detection of novel coronavirus (COVID-19) antigen in saliva sample, only for in vitro diagnostic use. The novel coronaviruses belong to the β genu 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 goldmixture. 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: 1/3/5/20/25 pc(s)
3. Plastic cup: 1/3/5/20/25 pc(s)
4. Pipette dropper: 1/3/5/20/25 pc(s)
5. Reaction tube: 1/3/5/20/25 pc(s)
6. 1 Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNINGS AND PRECAUTIONS

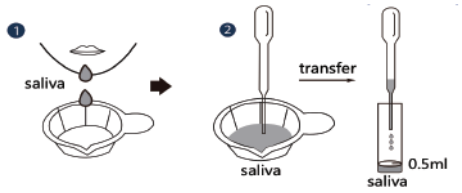
1. This product is a single-use in vitro diagnostic reagent. Do not reuse it. Do not use it if it is expired.
2. Each component of the kit cannot be used in batches.
3. The positive result obtained by using this kit needs further confirmation by other methods.
4. The temperature of the experimental environment should be avoided. The reaction temperature should be 10~30°C, 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. Avoid cross-contamination of saliva samples by using a new plastic cup and pipette dropper for each saliva sample.
8. The components of the kit and the waste produced by the test are treated as infectious pollutants.
9. 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°C to 30°C 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. Put your tongue on your upper jaw and bow your head to let saliva secrete naturally into a disposable plastic cup.
2. Use a dropper to transfer 0.5~1 ml of saliva from the plastic cup to the reaction tube.

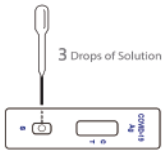


3. Saliva specimens may be stored at 2-8ºC for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20ºC. Frozen specimens should be thawed and mixed before testing.

PRIMARY SAMPLE COLLECTION, HANDING AND STORAGE

1.Specimen extraction
(1)Unscrew the lid of an extraction buffer. Add all of the extraction buffer into a reaction tube with 0.5~1mL saliva sample.
(2)Shake evenly, and keep the saliva still in the reaction tube for 1 minute.
(3)Shake the reaction tube again before performing the assay.

2.Detection operations:
(1)Bring the sample, test kit and other controls to equilibrate to room temperature prior to testing.
(2)Open a pouch containing a test cassette. Place the test cassette on a dry, horizontal work surface.
(3)Hold the dropper vertically and transfer 3 drops of saliva specimen to the sample well of the test cassette.
(4)Observe the results showed within 10-15 minutes, and the results showed after 15minutes 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 theincorrect 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 COVID-19 antigen in human saliva.
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 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.
4. 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.
5. 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.
6. 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 Saliva 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 saliva 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 Saliva Test Kit are satisfactory.

- Diagnostic Sensitivity and Specificity

  255 samples were collected from selected subjects, total 105 saliva samples from COVID-19 infected patients and 150 non-COVID-19 infected saliva 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	104
Negative	2	149	151
Total	105	150	255

Diagnostic Sensitivity: 103/(103+2)×100%=98.10%
Diagnostic Specificity: 149/(1+149)×100%=99.33%
Overall coincidence rate: (103+149)/ (103+1+2+149)×100%=98.82%

LITERATURE REFERENCES

[1]To, K. K.-W. et al. Consistent Detection of 2019 Novel Coronavirus in Saliva. Clin.Infect. Dis. (2020) doi:10.1093/cid/ciaa149.
[2]Kim, Y.-G. et al. Comparison between Saliva and Nasopharyngeal Swab Specimens for Detection of Respiratory Viruses by Multiplex Reverse Transcription-PCR. J. Clin. Microbiol. 55, 226–233 (2017).
[3]Wei YQ, Duan YC, Bi YH, et al. A novel carbon nanoparticle probe-based ultrasensitive lateral flow assay for rapid detection of Ebola virus. Chin J Biotech, 2018, 34(12): 2025–2034.

DEX OF SYMBOLS

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

Importer: Noviral Sweden AB
Västmannagatan 3
111 24 Stockholm, Sweden

EC REP