SARS-CoV-2 Antigen Rapid Detection Kit Instructions for Use

INTENDED USE

CAS-Envision SARS-CoV-2 Antigen Rapid Detection Kit is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human oral saliva specimen.
The test provides preliminary test results but cannot be used as the sole basis for treatment or other management decision.Positive results indicate the presence of viral antigens,but do not rule out bacterial infection or co-infection with other viruses.Negative results do not rule out SARS-CoV-2 infection.The results should be considered in the context of a personal recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay.

SUMMARY

Coronavirus is a large virus family, known to cause colds and more serious diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The new coronavirus is a new strain of coronavirus that has never been found in humans before. The International Committee on Classification of Viruses named the 2019 new coronavirus SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2), and the disease caused by it was named COVID-19 by the WHO.
The main transmission routes of SARS-CoV-2 are respiratory droplets and contact transmission. The transmission routes of Relative sensitivityaerosol and feces-oral still need to be further clarified.People infected with SARS-CoV-2 will have a range of symptoms, main symptoms include fever, fatigue and dry cough. In a few cases, nasal congestion, runny nose, sore throat, myalgia and diarrhea were found. Some will develop pneumonia, and some will be more serious or even death. The fatality rate of the virus is about 2% to 4%, but this is a very early percentage and may change as more information becomes available. At the same time, this does not mean that it is not serious.

PRINCIPLE

CAS-Envision SARS-CoV-2 Antigen Rapid Detection Kit (Lateral Flow Method) is based on the principle of Immunochromatography sandwich for determination of SARS-CoV-2 antigen extracted from the oral saliva specimen.
After adding the extracted specimen into the test cartridges,the specimen will move along the nitrocellulose membrane to the end of the absorbent paper by capillary action. When the SARS-CoV-2 antigen level in the specimen reaches or exceeds the target threshold, the line T(Test Region) will be colored (pre-embedded with SARS-CoV-2 N protein monoclonal antibody),which indicates a positive result. another visible colored band may appear at the line C (Control Region), indicating that the test has been performed correctly. When the SARS-CoV-2 antigen level in the specimen is zero or below the target threshold, the T line is not colored ,this indicates a negative result.

WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only;
2. Please follow the correct process for specimen collection and testing to avoid false or invalid results;
3. Do not reuse any kit components;
4. Please check the packaging before use. If it is damaged, poorly sealed or has expired, please do not use it;
5. Do not touch the reaction area of the test strip;
6. All specimens and used kits should be considered as a risk of infection.
7. After use, please dispose of the used test kit as biohazardous waste according to local requirements.

MATERIALS PROVIDED

1. 1 Foil pouch,contains:
   - 1 Saliva test cartridge
   - 1 Desiccant pouch
2. 1 Instructions for Use
3 1 QC card

STORAGE AND STABILITY

1.Store at 2~30℃;
2.The test cartridge should be used within 1 hour after taking out from the foiled pouch;
3. Keep away from sunlight, moisture and heat;
4. The product batch number, production and expiry date are printed on the outer packaging box.Under the correct storage conditions, the items in the kit are stable until the expiration date.

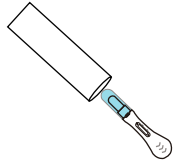
CAUTION BEFORE TEST

1.Do not put anything in your mouth, including food, beverages, medicine, chewing gum, and tobacco products, for at least 30 minutes before the sample is collected.
2.The test should be operated at room temperature (15-30℃).
3.Please read the instructions for use carefully before performing the test.
4.Do not read results after 30 minutes.

TEST PROCEDURE

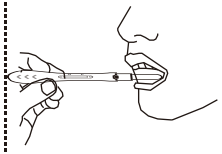
1. Remove the saliva test cartridge from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Cough deeply twice before collecting the samples.
3. Pull the blue cap off gently by holding the sides to expose the collection pad.
4. Hold the top portion of the device and place the collection pad into the mouth.
5.Rub the collection pad against the cheek and tongue gently in a circular motion about 10 times. Then place the collection pad in the mouth for about 1~2 minutes,and keep the device in a horizontal position,until the C line show up in the C region.
6. Remove the device from mouth as soon as the C line appears at the C rigion.
7. Place the cap onto the device, lay it on a flat surface.
8. Read results at 10-15minutes after removing device from mouth. Do not read results after 20 minutes.

THE PROCEDURE CARD



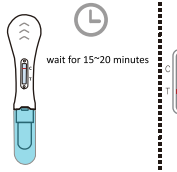
1.Open the aluminum foil bag and take out the saliva test cartridge.

2.Take off the cartridge cap.

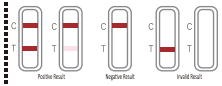


3.Place the absorbent pad beneath tongue for 2 minutes,wait the saliva liquid move upward until it reaches or moves over Line C.

4.Then put back the cap and lay down the test cartrideg on aflat surface.



5.Interpret the test result in 15 minutes,do not read the test result after 20 minutes.



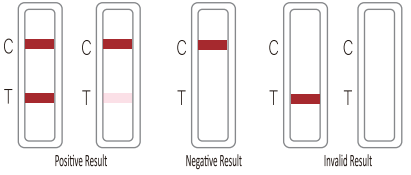
6.Read the results

RESULT INTERPRETATION

Positive Result
Colored bands appear at both test line (T) and control line (C) showing as following picture. It indicates a positive result for the SARS-CoV-2 antigen in the specimen.

Negative Result
Colored band appear at control line (C) only. It indicates that the concentrationof the SARS-CoV-2 antigen is zero or below the detection limit of the test.

Invalid Result
No visible colored band appear at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



REPORTING OF RESULTS

Positive Test:
Positive for the presence of SARS-CoV-2 antigen. Positive results indicate the presence of viral antigens,you have a very high probability of contracting SARS-CoV-2. 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.You must immediately take the necessary quarantine measures and go to the local hospital for further diagnosis.

Negative Test:
Negative results are presumptive. You have a low probability of contracting SARS-CoV-2. But negative test results do not preclude infection. If you still suspect that you or your family members are infected with SARS-CoV-2, you can go to the local medical institution for further testing by molecular nucleic acid testing.

Invalid Test:
The invalid result indicates that this test is invalid. Please read the instruction carefully again and repeat the test. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.If repeated test results are still invalid, consult the kit seller.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient liquid volume, adequate membrane wicking and correct procedural technique.

PERFORMANCE VERIFICATION

Sensitivity and Specificity:
Collected saliva samples use the saliva test cartridge from 118 patients with SARS-CoV-2 nucleic acid positive and 127 subjects with SARS-CoV-2 nucleic acid negative were tested simultaneously using the product and PCRmethod to evaluate the sensitivity, specificity and accuracy of the product; The test results were compared with PCR, The sensitivity, specificity and accuracy were calculated.
The oral saliva specimens test data statistics:

Relative sensitivity	93.2%	110/118
Relative specificity	99.2%	126/127
Accuracy	96.3%	236/245

Minimum detection limit:
Comparison test with the PCR kits, the LOD range finding was located as: 1:1000 titer of the contrived sample S2 , the Ct value of 32.06 at which the result was 100% +(F).When 1:10000 titer of the contrived sample S2 , the Ct value of 34.03 at which the result was +(F) and 67.7%. So Ct value of 32.06 was confirmed as the LOD.

Stability:
The three batches of products after 150 days of 37 ℃ thermal stability test, only in the 25pg/ml detection line and below appeared large fluctuations, other quality control concentration and negative performance are still stable, there is no obvious change, does not affect the normal use of the product.According to the stability test data, the shelf life of the kit is more than 18 months.

Cross-reactivity:
Professional test, there is no cross-reaction between the pathogen samples listed in the table below and SARS-CoV-2 Antigen Rapid Detection Kit.

S.N.	Potential Cross Reactant	Concentration Tested	Cross Reactivity (Yse/ No)
1	Human coronavirus 299E	10 ug/mL	NO
2	Human coronavirus OC43	10 ug/mL	NO
3	Human coronavirus NL63	10 ug/mL	NO
4	Human coronavirus HKU1	10 ug/mL	NO
5	Human metapneumovirus	10 ug/mL	NO
6	Human parainfluenza virus 1	10 ug/mL	NO
7	Human parainfluenza virus 2	10 ug/mL	NO
8	Human parainfluenza virus 3	10 ug/mL	NO
9	Human parainfluenza virus 4	10 ug/mL	NO
10	MERS	10 ug/mL	NO

Interference:
Professional test,There is no interference between the pathogen samples listed in the table below and SARS-CoV-2-Antigen Rapid Detection Kit.

S.N.	Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yse/ No)
1	Mycoplasma pneumoniae	50 ug/mL	NO
2	Avian Influenza(H7N9, H5N1)	5 ug/mL	NO
3	Influenza A(H1N1, H3N2)	5 ug/mL	NO
4	Influenza B	5 ug/mL	NO
5	Respiratory syncytial virus	50 ug/mL	NO
6	Staphylococcus aureus	10 ug/mL	NO
7	Epstein-Barr virus	30 ug/mL	NO
8	Mumps virus	10 ug/mL	NO
9	Varicella-zoster virus	10 ug/mL	NO
10	Bordetella pertussis	10 ug/mL	NO
11	Chlamydia pneumoniae	10 ug/mL	NO
12	Haemopjilus Influenza	10 ug/mL	NO
13	Legionella pneumophila	10 ug/mL	NO
14	Streptococcus pneumoniae	10 ug/mL	NO
15	Streptococcus pyogenes	10 ug/mL	NO
16	Mycobacterium tuberculosis	10 ug/mL	NO
17	Candida albicans	10 ug/mL	NO
18	Adenovirus	5 ug/mL	NO
19	Rhinovirus	10 ug/mL	NO
20	Enterovirus	10 ug/mL	NO
21	Normal nasal flush fluid	/	NO

LIMITATIONS OF PROCEDURE

1. This product can only be used to detect the N antigen of the SARS-CoV-2 in human oral saliva specimen ;
2. Positive test results do not rule out co-infections with other pathogens.Anegative test result does not rule out the possibility of infection with SARS-CoV-2.
3. Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay;
4. Using other non-provided consumables, such as test cartridges,etc.,may cause false negative results;
5.Please follow the standard procedure. Improper sample collection,improper sample storage,or repeated freezing and thawing of the sample will affect the test result.

HOOK EFFECT

Within the titer range of clinically positive samples of SARS-CoV-2 antigens, there is no hook effect in the test results of this product.

INDEX OF SYMBOL

IVD	*In Vitro* Diagnostic Use		See Instruction for Use
Σ	Tests per Kit		Manufacturing Date
LOT	Batch Number	EC REP	Authorized Representative
	Manufacturer		Do not reuse
	Expiry Date		Keep away from Sunlight
	Keep Dry	REF	Catalog #
30℃ 2℃	Store between 2~30℃		This Side Up

GENERAL INFORMATION

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