SARS-CoV-2 Antigen Rapid Detection Kit (Self-Test) Instructions for Use

INTENDED USE

CAS-Envision SARS-CoV-2 Antigen Rapid Detection Kit (Self-Test) is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human nasal vestibule swab or oral cavity and saliva swab 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 nasal vestibule swab or oral cavity and saliva swab 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 bag, contains:
   - 1 Test Cartridge
   - 1 Desiccant Pouch
2. 1 Biohazard bag, contains:
   - 1 Sample extraction tube
   - 1 Dripper
   - 1 Sample extraction solution
3. 1 Sterile swab
4. 1 Instructions for use
5. 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.The test should be operated at room temperature (15-30℃).
2.Please read the instructions for use carefully before performing the test.
3.Do not read results after 30 minutes.

SPECIMEN COLLECTION

Specimens collection may significantly affect the test result. Specimens should be collected carefully follow the following methods or infection control procedures.
Choose one of the following two ways to collect specimens as required.

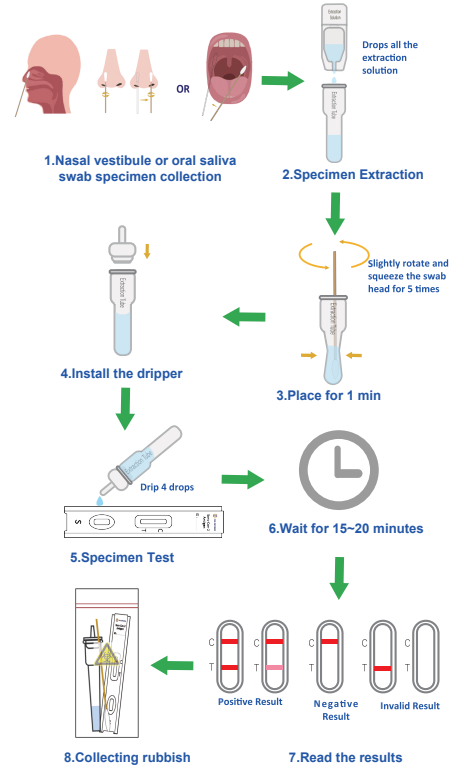
Nasal vestibule swab specimen collection:
1. Take out the sample collect swab included with the kit and carefully insert it into your nostrils 2-4cm until resistance is encountered.
2. Roll the swab against the nasal mucosa and wipe it back and forth 5 times to ensure adequate sample is collected.
3. Using the same swab to collect the sample from the other nostril with the same way.
4. Remove the swab and proceed to the next test.

Oral cavity and saliva swab specimen collection:
1. Do not put anything in your mouth, including food, beverages, medicine, chewing gum, and tobacco products, for at least 10 minutes before the sample is collected.
2. Cough twice before collecting the sample.
3. Take out the sample collect swab included with the kit. Rub the swab five times each along both sides of the inner wall of the mouth, upper jaw, sublingual, and on the surface of the tongue to collect as much saliva as possible from the entire mouth.
4.Remove the swab and proceed to the next test.

TEST PROCEDURE

1. Tear off the extraction solution package, and drops all the extraction solution into the extraction tube(A hole in the outer box to place the extraction tube).
2. Insert the swab with collected specimen into the sample extraction tube.
3. Squeeze and stir the swab head at least 5 times,let the extraction solution submerge past the swab head. Then soak for more than 1 minute to release the sample from the swab head into the extraction solution.
4. Remove the swab head from the extraction solution to close to the edge of the extraction tube, and squeeze the swab head as much as possible to dry it, to let more sample remain in the extraction tube.
5. Place the dripper firmly over the sample extraction tube.
6. Take out a test cartridge from the foiled pouch by tearing at the notch and place it on a level surface. Be careful not to touch the test area in the center of the test cartridge.
7. Drip 4 drops of extraction solution into the sample well of the test cartridge and start the timer.
8. Wait for 15-20 minutes and read the results. Results read after less than 15 minutes or more than 30 minutes are invalid.
9. At the end of the test, dispose of the sample extraction tube and test cartridge in the biosafety bag, seal and dispose of in accordance with local legal requirements.

THE PROCEDURE CARD

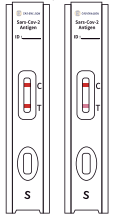


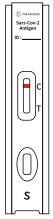
Before the test, use the browser to scan the QR code on the front of the outer box to watch the demo video and more detailed information.

RESULT INTERPRETATION

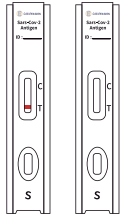
Positive Result
Colored bands appear at both test line (T) and control line (C) showing as following picture. It indicates a positive result for the SARS-CoV-2 antigen in the specimen.

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:
The nose swabs (anterior nasal cavity) and oral saliva swabs of 118 patients with novel Coronavirus nucleic acid positive and 127 subjects with novel Coronavirus nucleic acid negative were tested simultaneously using the product and PCR method to evaluate the sensitivity, specificity and accuracy of the product;The nasal and oral swabs test results were compared with PCR, The sensitivity, specificity and accuracy were calculated .
The nasal swabs test data statistics :

Relative sensitivity	97.5%	115/118
Relative specificity	99.2%	126/127
accuracy	98.4%	241/245

The oral saliva swabs test data statistics:

Relative sensitivity	95.8%	113/118
Relative specificity	98.4%	125/127
accuracy	97.1%	238/245

Minimum detection limit:
Comparison test with The PCR kits， the LOD range finding was located as: 1:10000 titer of the contrived sampl(the Ct value = 34), which the three repeated tests result was 100% +(F).When 1:100000 titer of the contrived sample , the Ct value of 36.227 at which the result was +(F) and 67.7%. So ct value of 34 by was confirmed as the LOD in nasal swabs sample.

Stability:
The three batches of products after 35 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, do es not affect the normal use of the product.According to the stability test data, the shelf life of the kit is more than one and a half years.

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 nasal vestibule swab or oral cavity and saliva swab;
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 swabs, extracts,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°C 2°C	Store between 2~30°C		This Side Up

Shenzhen CAS-Envision Medical Technology Co., Ltd.
Add: 4F, Bldg 4, Tusincere Technology Park, No. 333,Longfei Avenue,Longcheng,Longgang,Shenzhen, Guangdong,China
Tel:+86-755-28709890 Fax:+86-755-28705580
Website: www.cas-envision.com

EC REP
Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

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