IVD

COVID-19 Salivary Antigen Rapid Test Kit（Colloidal Gold）

REF **ICOVS-702G-12 / ICOVS-702G-13**

For professional use only.

INTENDED USE

COVID-19 Salivary Antigen Rapid Test Kit (Colloidal Gold) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus (SARS-CoV-2) antigen from the saliva specimens.
The test provides preliminary test results. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.
This product can not be used as the basis to diagnose or exclude SARS-CoV-2 infection.

SUMMARY

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.

PRINCIPLE

COVID-19 Salivary Antigen Rapid Test Kit (Colloidal Gold) is based on the principle of capture immunoassay for determination of SARS-CoV-2 antigen from the saliva specimens.
When the specimen is added into the test device, the specimen is absorbed into the device by capillary action.
If the sample contain novel coronavirus antigen, the antigen combined with the colloidal gold labeled novel coronavirus antibody, and when the novel coronavirus antigen level in the specimen is at or above the target cut-off, and the immune complex further binds to the coated antigen in the T line and this produces a colored test band that indicates a positive result.
When the novel coronavirus Antigen level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region of the device. This indicates a negative result.
To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

MATERIALS PROVIDED

Package Specification	1 T/box	20 T/box
Catalogue number	ICOVS-702G-12	ICOVS-702G-13
Test Kit pouch	1	20
Disposable cup	1	20
Instruction for use	1	1

MATERIALS REQUIRED BUT NOT SUPPLIED

Clock or timer, specimen collection container, biohazard waste container. personal protection equipment.

STORAGE

1. Store at 4~30℃ in the sealed pouch up to the expiration date printed on the package. Do not freeze.
2. The test cassette should be used within 1 hour after taking out from the foil pouch.
3. Keep away from sunlight, moisture and heat.
4. Kit contents are stable until the expiration date printed on the outer box.

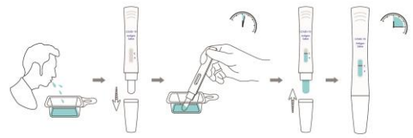
PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in the collection, handling, storage and disposal of patient specimens and used kit contents. And follow biosafety level 2 or higher guidelines.
3. Wear appropriate personal protective equipment (e.g. gowns, gloves, eye protection) when handing the contents of this kit.
4. Proper specimen collection storage and transport are critical to the performance of this test.
5. Discard after first use. The test cannot be used more than once.
6. Do not touch the reaction area of test strip.
7. Do not use the test kit beyond the expiration date.
8. Do not use the kit if the pouch is punctured or not well sealed.
9. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
10. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
11. Disposal of the diagnostic: All specimens and the used-kit have the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.
12. The results should be read immediately after 15min of detection, and the results will be invalid after 30 minutes.
13. The product is applicable to saliva specimens. Using other specimen types may cause inaccurate or invalid test results.
14. The test detects the SARS-CoV-2 nucleocapsid protein, and the test result is not affected by the spike protein from SARS-CoV-2 genetic variants.

TEST PROCEDURE

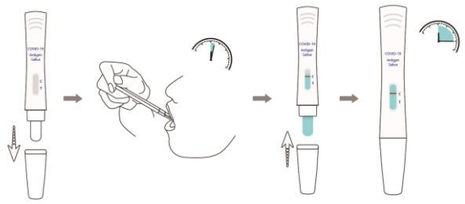
Allow the test device, and specimen to equilibrate to room temperature (10°C ~30°C) prior to testing.

TEST METHOD 1



1. Collect enough fresh saliva in a single use disposable cup(At least 2 ml).
2. Open aluminum foil bag take out the test card lid.
3. Place the test card absorbing rod end for saliva collection into the saliva,let it immerse in saliva and absorb saliva fully.
4. Keep the test card upright and let the saliva liquid move forward until the control line (C) appears, then put the cover back on the test card and lay down the test card on the table.
5.Read the test results at 15 minutes. Do not read test results after 30 minutes.

TEST METHOD 2

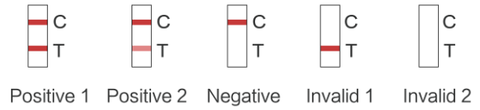


1. Open aluminum foil bag take out the card lid.
2. Place the test card absorbing rod beneath.
3. Keep the test card upright and let the saliva liquid move forward until the control line (C) appears, then put the cover back on the test card and lay down the test card on the table.
4. Read the test results at 15 minutes. Do not read test results after 30 minutes.

NOTE:

1. When sampling, gently hold it in mouth and let saliva naturally adsorb on the test cassette.
2. Don`t bite the test cassette with teeth.
3. Any saliva specimen is appropriate for testing but the saliva specimen collected in the morning, before mouth rinsed, eating or drinking, is recommended.
4. Proper specimen collection, storage, and transport are critical to the performance of this test.
5. Specimens should be tested as soon as possible after collection.

INTERPRETATION OF RESULTS



Positive Result
Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the novel coronavirus antigen in the specimen.
Negative Result
Colored band appear at control line (C) only. It indicates that the concentration of the novel coronavirus antigen is zero or below the detection limit of the test.
Invalid Result
No colored band appears at control line (C). Whatever colored bands appear at test line (T), the test results will be invalid

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 specimen volume, adequate membrane wicking and correct procedural technique.
Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE

1. This reagent is designed to detect Antigen of SARS-CoV-2 in saliva specimens
2. This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antigens.
3. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.
4. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5-7 of illness are more likely to be tested negative compared to a RT-PCR assay.
5. The test result of this reagent is for clinical reference only, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
6. Limited by the method of antigen detection reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.
7. Positive test results do not rule out co-infections with other pathogens. A negative result of this reagent can be caused by:
1) Improper sample collection, improper sample transfer or handing, the virus titer in the sample is too low;
2) The level of SARS-CoV-2 antigen is below the

detection limit of the test.
3) Variations in viral genes may cause changes in antigen determinants.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

The limit of detection (LoD) for the COVID-19 Salivary Antigen Rapid Test Kit (Colloidal Gold) was established in an analytical sensitivity study performed with one virus strain and one recombinant nucleocapsid protein. The LoD was confirmed in the following table

No.	Item	Limit of Detection
1	SARS-CoV-2 Virus	100 $TCID_{50}$/ml
2	SARS-CoV-2, Recombinant nucleocapsid protein	250pg/ml

Cross Reactivity

The cross reactivity of the Rapid SARS-CoV-2 Antigen Test Card was evaluated with a total of 28 microorganisms. The microorganisms tested in the following table does not cross-react.

Microorganisms	Concentrations
Human coronavirus 229E	2.0 x 10^6 $TCID_{50}$/mL
Human coronavirus OC43	2.0 x 10^6 $TCID_{50}$/mL
Human coronavirus NL63	2.0 x 10^6 $TCID_{50}$/mL
Parainfluenza virus 1	2.0 x 10^6 $TCID_{50}$/mL
Parainfluenza virus 2	2.0 x 10^6 $TCID_{50}$/mL
Parainfluenza virus 3	2.0 x 10^6 $TCID_{50}$/mL
Enterovirus EV71	2.0 x 10^6 $TCID_{50}$/mL
Respiratory syncytial virus	2.0 x 10^6 $TCID_{50}$/mL
Rhinovirus	2.0 x 10^6 $TCID_{50}$/mL
Influenza A virus (H1N1)	2.0 x 10^6 $TCID_{50}$/mL
Influenza A virus (H3N2)	2.0 x 10^6 $TCID_{50}$/mL
Influenza B virus (Yamagata)	2.0 x 10^6 $TCID_{50}$/mL
Influenza B virus (Victoria)	2.0 x 10^6 $TCID_{50}$/mL
Adeno virus	2.0 x 10^6 $TCID_{50}$/mL
HCoV-2-HKU1	2.0 x 10^6 $TCID_{50}$/mL
MERS-coronavirus	1.0 x 10^6 $TCID_{50}$/mL
Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
Streptococcus pneumoniae	2.0 x 10^6 CFU/mL
Streptococcus pyogenes	2.0 x 10^6 CFU/mL
Bordetella pertussis	2.0 x 10^6 CFU/mL
Mycobacterium tuberculosis	2.0 x 10^6 CFU/mL
Legionella pneumophila	2.0 x 10^6 CFU/mL
Mycoplasma pneumoniae	2.0 x 10^6 U/mL
Haemophilus influenzae	2.0 x 10^6 CFU/mL
Candida albicans	2.0 x 10^6 CFU/mL
Staphylococcus aureus	2.0 x 10^6 CFU/mL
Pseudomonas aeruginosa	2.0 x 10^6 CFU/mL
Escherichia coli	2.0 x 10^6 CFU/mL

Interference

Endogenous Substances

COVID-19 Salivary Antigen Rapid Test Kit (Colloidal Gold) has tested samples with common endogenous substances. The results showed that these substances had no effect on the specificity of the assay up to the listed concentration.

Substances	Concentrations
Whole Blood	1%v/v
Mucin	2%w/v
Tobramycin	0.0004%w/v
Ricola(Menthol)	0.15%w/v
Chloraseptic(Benzocaine)	0.15%w/v
Mupirocin	0.25%w/v
Tamiflu(Oseltamivir Phosphate)	0.5%w/v
Homeopathic(Alkalol)	10%v/v
CVS Nasal Drops(Phenylephrine)	15%v/v
Afrin(Oxymetazoline)	15%v/v
CVS Nasal Spray(Cromolyn)	15%v/v
Fluticasone Propionate	5%v/v
Zicam	5%w/v

Accuracy

The COVID-19 Salivary Antigen Rapid Test Kit (Colloidal Gold) was established with 1343 saliva specimens collected from individual symptomatic patients (within 7-14 days of onset) who were suspected of COVID-19. The following table summarizes the accuracy of the COVID-19 Salivary Antigen Rapid Test Kit (Colloidal Gold) compared to RT-PCR.

Evaluated Reagent Results	RT-PCR Results		
	Positive (+)	Negative (-)	Total
Positive (+)	130	8	138
Negative (-)	5	1200	1205
Total	135	1208	1343

Sensitivity (PPA) = 130/135×100% = 96.3%
(95%CI: 91.57%～98.79%)
Specificity (NPA) = 1200/1208×100% = 99.34%
(95% CI: 98.70% -99.71%)
Accuracy (OPA) = 1330/1343×100%=99.03%
(95%CI:98.35%～98.48%)

Precision

The with-day and between-day precision, the Intra-round and between-round precision, the precision between the operator and the laboratory is good，The reagent performance is stable.

REFERENCE

1. Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected. Interim guidance. World Health Organization. 13 March 2020.
2. Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19). World Health Organization. 16-24 February 2020.
3. The Epidemiological Characteristics of an Outbreak of 2019 Novel Coronavirus Diseases (COVID-19). Chinese Center for Disease Control and Prevention. CCDCWeekly,2(8):113-122, 2020.

INDEX OF SYMBOL

IVD	In Vitro Diagnostic Medical Device		Manufacturer
	Date of manufacture		Use-by date
EC REP	Authorized Representative	LOT	Batch code
	Caution		See Instruction for use
	Keep away from sunlight		Keep Dry
	Biological Risks		Do not reuse
REF	Catalogue number	4°C 30°C	Store between 4～30° C

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EC REP
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