SARS-CoV-2 Antigen Rapid Test Cassette

[Product Name]

SARS-CoV-2 Antigen Rapid Test Cassette

[Packing Specification]

1 test/kit

[Catalogue number]

G1S1-X2

[Intended Use]

The SARS-CoV-2 Antigen Rapid Test Cassette is a colloidal gold immunochromatography assay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in human saliva, nasal swab from persons suspected by their healthcare provider of having COVID-19 within the first 7 days after the onset of symptoms.

The SARS-CoV-2 Antigen Rapid Test Cassette is suitable for clinical laboratory personnel with specific instruction and training in in vitro diagnostic techniques and appropriate infection control, as well as those with similar training at the point of care.

[Test Principle]

SARS-CoV-2 Antigen Rapid Test Cassette is an immunoassay based on the principle of the double antibody-sandwich technique. The SARS-CoV-2 Antigen Rapid Test Cassette is designed to detect nucleocapsid antigen from the SARS-CoV-2 in human saliva and nasal swab, from patients who are suspected of SARS-CoV-2 infection by their healthcare provider. During testing, a specimen migrates upward by capillary action. The SARS-CoV-2 antigens if present in the specimen will bind to the antibody conjugates. The immune complex is then captured on the membrane by the pre-coated SARS-CoV-2 nucleocapsid protein monoclonal antibody, and a visible colored line will show up in the test line region indicating a positive result. In the absence of SARS-CoV-2 antigens, a colored line will not form in the test line region indicating a negative result.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Coronaviruses belong to Nidovirales and Coronaviridae. According to serotypes and genomic characteristics, coronaviruses are divided into four genera: α, β, γ and δ. Among them, there are 7 coronavirus infecting human beings. 229E and NL63 belong to α genus; OC43 and HKU1, middle east respiratory syndrome related coronavirus (MERSr-CoV), severe acute respiratory syndrome associated coronavirus (SARSr-CoV), and the novel coronaviruses belong to the β genus. The main manifestations of SARS-CoV-2 infection include fever, fatigue, dry cough and dyspnea. It may rapidly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base disturbance, and even endanger life. The SARS-CoV-2 is mainly transmitted through direct contact with secretions or aerosol and droplets. Laboratory detection methods for SARS-CoV-2 mainly include virus isolation, nucleic acid detection and so on.

[Main Components]

Test Cassette	Saliva Collector
Extraction Tube	Extraction Reagent
Sterilized Swab	

Note: The different lots of components cannot be exchanged. Sterilized swab has obtained CE certification.

[Storage Conditions and Expiration Date]

Storage conditions and expiration date: The kit should be stored at 2~30℃, and is valid provisionally for 24 months. Once open the pouch, the test should be used within 30min.

Don't freeze, please use within the expiration date.

Date of manufacture and expire date (see label).

[Sample Requirements]

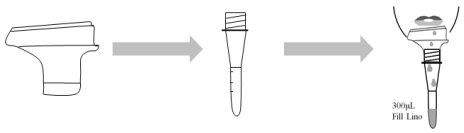
1. Applicable samples:

Saliva, Nasal swab.

1) Saliva

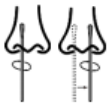
Do not put anything in your mouth, including food, drink, gum or tobacco products, etc. at least 30 minutes before collection.

Collect saliva with saliva collector and extraction tube， screw the saliva collector to extraction tube. Place the saliva collector close to lips and spit the saliva into the saliva collector. The mount of saliva needs to reach the graduation line (about 300μL).



2） Nasal swab

Carefully insert soft end of swab into one nostril. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril. Roll swab 3-4 times along the mucosa inside the nostril. Leave swab in the nostril for several seconds. Using the same swab, repeat this process for the other nostril. Withdraw swab from the nasal cavity.



Note：

1） Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts.

2） Do not use specimens that are obviously contaminate with blood, as it may interfere with the flow of sample with the interpretation of test results.

2. Sample storage

1) For saliva sample: Freshly collected specimens should be processed as soon as possible, but no later than 1 hour after specimen collection. Specimen collected maybe stored at 2-8℃for no more than 24 hours; Store at-70℃for a long time, but avoid repeated freeze-thaw cycles.

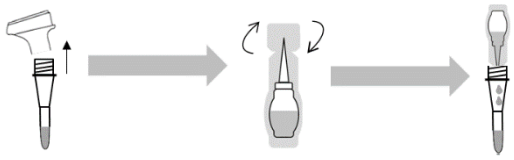
2) For nasal swabs: Freshly collected specimens should be processed as soon as possible, but no later than 30min after specimen collection. Specimen collected maybe stored at 2-8℃ for no more than 24 hours; store at-70℃ for a long time, but avoid repeated freeze-thaw cycles.

[Test Method]

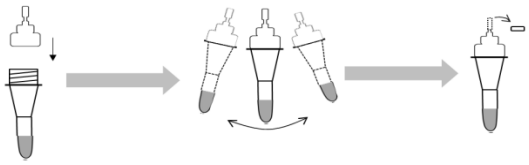
1. Samples preparation

(1) For saliva sample：

1) Open the extraction reagent and drop all the liquid into the extraction tube.



2) Cover the extraction tube, shake at least 3 times till the saliva and the extraction reagent fully mixed, and squeeze the extraction tube 10 times at least to make the saliva fully mixed.



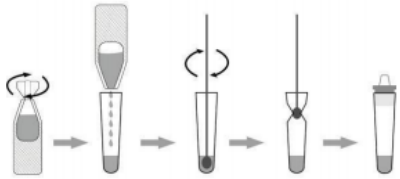
(2) For nasal swab：

1) Open the extraction reagent and drop all the liquid into the extraction tube.

2) Insert the swab into the extraction tube which contains the extraction reagent. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that the solution is expressed and reabsorbed from the swab.

3) Pinch the extraction tube with fingers and elute the liquid on the swab as far as possible into the extraction reagent, then pull out the swab. The extracted solution will be used as test specimen.

4) Buckle the dripper.

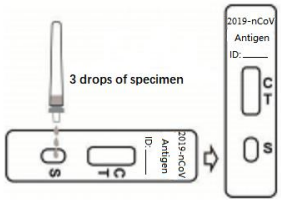


2. **Samples testing**

1) Remove the test cassette from the sealed pouch.

2) Reverse the specimen extraction tube, holding the specimen extraction tube upright, add 3 drops (about 90μL) of the sample to be tested into each sample hole, then start the timer.

3) Wait for colored lines to appear. Interpret the test results at 15 minutes. Do not read results after 20 minutes.

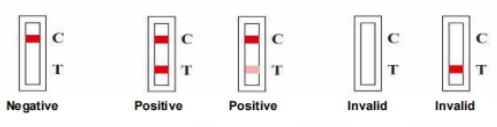


[Interpretation of Test Results]

1. Positive: Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T). Positive for the presence of SARS-CoV-2 nucleocapsid antigen.

2. Negative: One colored line appears in the control region (C), no line appears in the test region (T), negative results are presumptive, the result needs further confirmation.

3. Invalid: Control line fails to appear, insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cassette.



[Quality Control]

Internal Control:

Internal procedural controls are included in the test. A colored line in the control line region (C) is one internal procedural control. It confirms sufficient sample volume and correct procedural engineering.

External Positive and Negative Controls:

Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed.

Users should follow the appropriate regulations or guidelines to considering the external quality control test using the positive control and the negative control.

[Limitations]

1. The SARS-CoV-2 Antigen Rapid Test Cassette is limited to provide a qualitative detection and used to aid diagnosis.
2. Positive results indicate the presence of viral antigens 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.
3. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with SARS-CoV-2, or in those who have been in contact with the virus. A comprehensive analysis should be carried out based on the patient's recent exposure history, medical history, and clinical symptoms and signs related to SARS-CoV-2, and should be confirmed by molecular testing.
4. A physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
5. A negative result can occur if the quantity of antigens for the SARS-CoV-2 virus present in the specimen is below the detection threshold of the assay, or the virus has undergone minor amino acid mutation(s) in the target epitope region recognized by the monoclonal antibodies utilized in the test.
6. Proper specimen collection is critical, and failure to follow the procedure may give inaccurate results. Improper specimen collection, improper specimen storage or repeated freezing and thawing of specimens can lead to inaccurate results.

[Performance Characteristics]

Analytical Sensitivity (Limit of Detection):

The limit of detection was determined with a quantified SARS-CoV-2 virus and has been evaluated at 2×10^2 $TCID_{50}$/mL.

Clinical Evaluation:

1) Saliva

The clinical performance of the SARS-CoV-2 Antigen Rapid Test Cassette was determined by testing 103 positive and 108 negative samples for SARS-CoV-2 antigen with a sensitivity of 90.29% (95% CI: 82.87%-95.25%) and a specificity of 100% (95% CI: 96.64%-100%) determined by saliva Clinical specimens were determined to be positive or negative using an RT-PCR reference method.

Table 1: SARS-CoV-2 Antigen Rapid Test Cassette vs. RT-PCR

		RT-PCR		total
		Positive	Negative	
SARS-CoV-2 Antigen Rapid Test Cassette	Positive	93	0	93
	Negative	10	108	118
total		103	108	211

Relative Sensitivity: 90.29 % (82.87%-95.25%) *
Relative Specificity: 100 % (96.64%-100%) *
Overall Agreement: 95.26 % (91.46 %-97.70 %) *
*95% Confidence Interval

2) Nasal Swab

The clinical performance of the SARS-CoV-2 Antigen Rapid Test Cassette was determined by testing 101 positive and 108 negative samples for SARS-CoV-2 antigen with a sensitivity of 90.10% (95% CI: 82.54%-95.15%) and a specificity of 99.07% (95% CI: 94.95%-99.98%) determined by nasal swab clinical specimens were determined to be positive or negative using an RT-PCR reference method.

Table 2: SARS-CoV-2 Antigen Rapid Test Cassette vs. RT-PCR

		RT-PCR		total
		Positive	Negative	
SARS-CoV-2 Antigen Rapid Test Cassette	Positive	91	1	92
	Negative	10	107	117
total		101	108	209

Relative Sensitivity: 90.10 % (82.54%-95.15%) *
Relative Specificity: 99.07 % (94.95%-99.98%) *
Overall Agreement: 94.74 % (90.78 %-97.34 %) *
*95% Confidence Interval

Cross reactivity (analytical specificity) and microbial interference:

Cross-reactivity was assessed by examining the other pathogens and microorganisms in nasal/oral cavity that may have symptoms similar to the SARS-CoV-2 infection.

Each of the microorganisms were tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (400 $TCID_{50}$/mL). No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

Pathogenic microorganism name		Concentration
virus	Coronavirus 229E	1.0×10^6 PFU/mL
	Coronavirus OC43	1.0×10^6 PFU/mL
	Coronavirus HKU1	1.0×10^6 PFU/mL
	Coronavirus NL63	1.0×10^6 PFU/mL
	MERSr-CoV	1.0×10^6 PFU/mL
	New Type A H1N1 Influenza Virus (2009)	1.0×10^6 PFU/mL
	Seasonal H1N1 influenza virus	1.0×10^6 PFU/mL
	H3N2	1.0×10^6 PFU/mL
	Influenza B Yamagata	1.0×10^6 PFU/mL
	Influenza B Victoria	1.0×10^6 PFU/mL
	Respiratory Syncytial Virus Type A	1.0×10^6 PFU/mL
	Respiratory Syncytial Virus Type B	1.0×10^6 PFU/mL
	Parainfluenza virus type 1	1.0×10^6 PFU/mL
	Parainfluenza virus type 2	1.0×10^6 PFU/mL
	Parainfluenza virus type 3	1.0×10^6 PFU/mL
	Rhinovirus	1.0×10^6 PFU/mL
	Adenovirus type 3	1.0×10^6 PFU/mL
	Adenovirus type 7	1.0×10^6 PFU/mL
	Enterovirus	1.0×10^6 PFU/mL
	Human metapneumovirus	1.0×10^6 PFU/mL
	Epstein-Barr virus	1.0×10^6 PFU/mL
	Measles virus	1.0×10^6 PFU/mL
	Human cytomegalovirus	1.0×10^6 PFU/mL
	Mumps virus	1.0×10^6 PFU/mL
	Varicella-zoster virus	1.0×10^6 PFU/mL
bacterial	Mycoplasma pneumoniae	1.0×10^6 CFU/mL
	Legionella	1.0×10^6 CFU/mL
	Bacillus pertussis	1.0×10^6 CFU/mL
	Haemophilus influenzae	1.0×10^6 CFU/mL
	Staphylococcus aureus	1.0×10^6 CFU/mL
	Streptococcus pneumoniae	1.0×10^6 CFU/mL
	Streptococcus pyogenes	1.0×10^6 CFU/mL
	Klebsiella pneumoniae	1.0×10^6 CFU/mL
Fungus	Aspergillus fumigatus	1.0×10^6 CFU/mL
	Candida albicans	1.0×10^6 CFU/mL
	Candida glabrata	1.0×10^6 CFU/mL
	Cryptococcus neoformans	1.0×10^6 CFU/mL

Interfering Substances:

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect test performance of the SARS-CoV-2 Antigen Rapid Test Cassette.

(1) Endogenous factor

Interfering substances	Add concentration/amount
Mucin	1.35mg/mL
Whole Blood	7.5%

(2) Exogenous factor

Drug name	Product name	Add concentration/amount
Phenylephrine	Phenylephrine Hydrochloride Eye Drops	50%(V/V)
Oxymetazoline	Oxymetazoline Hydrochloride Nasal Drops	50%(V/V)
Sodium chloride (with preservatives)	Buffered saline	50%(V/V)

Beclomethasone	Beclomethasone Dipropionate Cream	2.5mg/mL
Dexamethasone	Tobramycin Dexamethasone Eye Drops	5μg/mL
Flunisolide	Triamcinolone-urea ointment	10mg/mL
Triamcinolone acetonide	Triamcinolone Acetate Urea Cream	10mg/mL
Budesonide	Reynolds Court	0.52nmol/L
Mometasone	Mometasone furoate cream	10mg/mL
Fluticasone	Fluticasone Propionate Cream	5mg/mL
Histamine Hydrochloride	Histamine human immunoglobulin	3mg/mL
alpha interferon	Andaphine	1000IU/mL
Zanamivir	Zanamivir inhalation powder mist	5mg/mL
Ribavirin	Ribavirin	142ng/mL
Oseltamivir	Duffy	0.15mg/mL
Peramivir	Li Wei	3.3mg/mL
Lopinavir/Ritonavir	Klitsch	4μg/mL, 1μg/mL
Abidor	Enlexin	0.1g/mL
Levofloxacin	Levofloxacin Hydrochloride Capsules	0.1g/mL
Azithromycin	Azithromycin tablets	0.25g/mL
Ceftriaxone	Ceftriaxone Sodium for Injection	2.5g/mL
Meropenem	Meropenem for Injection	0.5g/mL
Tobramycin	Dian Shu	48μg/mL

[Precautions]

1. For in vitro diagnostic use only, please read this instruction for use carefully before testing. Please use it within the expiration date.
2. This kit does not contain active human or animal derived substances.
3. Operators should be trained and operate in strict accordance with the instructions.
4. The sample processing is operated in the biosafety cabinet to prevent environmental pollution and protect the operator.
5. The waste materials after the experiment, such as tips, can be discarded only after harmless treatment. Tips used in sample-handling should be put into the waste tank containing 1% hypochlorite. After the experiment, use 1% hypochlorite or 75% ethanol to treat the operation table, and then irradiate with ultraviolet lamp for 25-30 minutes.
6. Due to the characteristics of swabs and virus infection process, there may be false negative results caused by insufficient samples volume. It should combine with other clinical diagnosis and treatment information for a comprehensive diagnosis and retested if necessary.

[References]

1. "General Guidelines for Biosafety in Microbiology and Biomedical Laboratories.

[Instruction of symbol]

IVD	*In vitro* diagnostic medical device		Manufacturer
	Consult instructions for use or consult electronic instructions for use		Temperature limit
	Use-by date		Keep dry
	Date of manufacture	REF	Catalogue number
LOT	Batch code		Fragile, handle with care
	Keep away from sunlight		Do not re-use
EC REP	Authorized representative in the European Community/ European Union		

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