SARS-CoV-2 Antigen Test Kit CE

PRODUCT NAME

Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2) Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay)

PACKING

25T/Kit

CATALOGUE NO.

SC0202

INTENDED USE

The SARS-CoV-2 Antigen Test Kit is an immunochromatographic test system for the rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen in human nasal basin or pharyngeal cavity and saliva specimens, can be used for diagnosis of coronavirus infection disease (COVID-19) in vitro, which is caused by SARS-CoV-2.

The SARS-CoV-2 Antigen Test kit provides preliminary test results, with negative results don't preclude SARS-CoV-2 infection. Cannot be used as the sole basis for treatment or other management decision. For in vitro diagnostic use only.

PRINCIPLE

The SARS-CoV-2 Antigen Test Kit is based on colloidal gold immunochromatography method to detect SARS-CoV-2 N protein in respiratory secretions and other specimens. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the gold-labeled antibody, and flows across the precoated membrane.

The SARS-CoV-2 antigen in specimen captured by the gold-labeled antibody S1a bound to antibody S1 immobilized in the Test Region (T) of the membrane, and this produces a colored test band that indicates a positive result.

When there is no SARS-CoV-2 antigen in the specimen or the concentration is lower than the detection limit of the test, there is not a visible colored band in the Test Region (T) 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.

MAJOR COMPONENTS

Material Provided

Test cassette (25 pcs)
Extraction tube (25 pcs, contains extraction buffer)
Swab (25 pcs)
Positive control (1×1 mL)
Negative control (1×1 mL)

Material Required but Not Provided

Timer, Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
Appropriate biohazard waste container and disinfectants.

STORAGE CONDITION

The test card is stable for 12 months (while sealed in an aluminum foil bag) if stored at 2～30°C. When the test environment humidity is more than 60%, the test card needs to be used immediately after the opening of the aluminum foil bag. When the test environment humidity is less than 60%, the test card needs to be used within 1 hour after the opening of the aluminum foil bag.

SPECIMEN COLLECTION AND PREPARATION

Specimen collection:

1. It is applicable to the diagnosis of the Novel coronavirus from the samples of nasopharyngeal, oropharyngeal and saliva swab. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.
2. For the sampling of nasopharyngeal swabs, the sterile swab provided in this kit should be completely inserted into the nasal basin and swabbed several times to collect the mucus epidermal cells.
3. For sampling of oropharyngeal swabs, the sterile swab provided in this kit should be completely inserted into the pharynx, tonsils and other inflamed areas. Avoid touching your tongue, cheeks and teeth with cotton swabs during sampling.
4. It is recommended to collect sample from nasopharyngeal for more accurate results.
5. For saliva swab completely insert the saliva swab supplied in this kit into the mouth, and stir slowly, at least 20 seconds to enough saliva into saliva swab.

REQUIREMENTS OF SPECIMENS

Swab Specimens

1. Completely insert the sterilized swab supplied in this kit into the nasal basin or pharyngeal cavity, and swab several times to collected the epidermal cell of the mucus. It is recommended to collect sample from nasal basin for more accurate results.
2. Unscrew the nozzle cap, then place the patient swab sample into the extraction tube. Roll the swab head against the inside of the extraction tube at least 3 times, and then wait for 1 minute.
3. Remove the swab while squeezing the swab head against the inside of the tube to expel as much liquid as possible from the swab. Dispose of the used Swab in your biohazard waste.
4. Press the nozzle cap tightly onto the tube

Saliva Specimens

1. Unscrew the nozzle cap, then place the patient saliva swab sample into the extraction tube. Roll the swab head against the inside of the extraction tube at least 3 times, and then wait for 1 minute.
2. Press the nozzle cap tightly onto the tube.

TEST PROCEDURE

1. Take out the test card from the aluminum foil bag and lay it flat on the test bench.
2. Add 4 drops of extracted specimen to the specimen well of the test device.
3. Read the results within 15 minutes.

NOTE: The experiment should be done at 15~30℃.humidity 35%～85%.

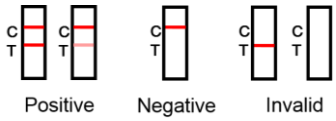
QUALITY CONTROL PROCEDURE

1. Take out the test card from the aluminum foil bag and lay it flat on the test bench.
2. Add 4 drops of positive control / negative control to the specimen well of the test device.
3. Read the results within 15 minutes.

NOTE: If the test result does not meet the requirements, please contact the manufacturer.

INTERPRETATION OF RESULTS

1. The presence of two lines (Test and Control), regardless of the intensity of the test line, indicates a positive result.
2. A single Control Line indicates a negative result.
3. If the control line does not appear, the results are invalid and the test should be repeated.



The results must be interpreted in 10 minutes.

LIMITATION OF METHODOLOGY

1. The Novel SARS-CoV-2 Antigen Test Kit is an acute-phase screening test for qualitative detection. Sample collected may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.
2. The Novel SARS-CoV-2 Antigen Test Kit detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present, therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
3. A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if poor quality specimen is obtained.
4. Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
5. Positive test results do not rule out co-infections with other pathogens.
6. Negative test results are not intended to rule in other coronavirus infection except the SARS-CoV-2.
7. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children List.
8. A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or PCR.

PERFORMANCE CHARACTERISTICS

1. Sensitivity & Specificity

Nasopharyngeal, oropharyngeal and saliva swab specimens from 273 patients, which included 73 COVID-19 positive and 200 COVID-19 negative results confirmed by clinical diagnosis judgement. The result of clinical evaluation of SARS-CoV-2 Antigen Test Kit was as follows:

Method		PCR		Total Results
SARS-CoV-2 Antigen Test Kit	Result	Positive	Negative	
	Positive	70	0	70
	Negative	3	200	203
Total Results		73	200	273
Sensitivity		95.9% (95%CI:89.8%~96.9%)		
Specificity		>99.9% (95%CI:97.6%~100.3%)		
Accuracy		98.9% (95%CI:97.2%~99.1%)		

2. Limit of Detection (LoD)

2019-nCoV Concentration	1 X 10^6 $TCID_{50}$/mL					
Dilution	1/100	1/200	1/400	1/800	1/1600	1/3200
Concentration in Dilution tested ($TCID_{50}$/ml)	1X10^4	5X10^3	2.5X 10^3	1.25X10^3	6.25X10^2	3.125X10^2
Rates of 20 replicates (%)	100(20/20)	100(20/20)	100(20/20)	100(20/20)	100(20/20)	10(2/20)
Limit of detection	6.25X$10^2$$TCID_{50}$/mL					

3. Interference experiment

The following substances were tested at the concentration shown, and no interference was found.

Mucin	100μg/mL	Acetylsalicylic acid	3.0 mM
Whole Blood	5% (v/v)	Ibuprofen	2.5 mM
Biotin	100μg/mL	Mupirocin	10 mg/mL
Neo-Synephrine (Phenylephrine)	5%(v/v)	Tobramycin	10μg/mL
Afrin Nasal Spray (Oxymetazoline)	5%(v/v)	Erythromycin	50uM
Saline Nasal Spray	5%(v/v)	Ciprofloxacin	50uM
Homeopathic	5%(v/v)	Ceftriaxone	110mg/mL
Sodium Cromoglycate	10 mg/mL	Meropenem	3.7μg/mL
Olopatadine Hydrochloride	10 mg/mL	Tobramycin	100μg/mL
Zanamivir	5 mg/mL	Histamine Hydrochloride	100μg/mL
Oseltamivir	10 mg/mL	Peramivir	1mmol/mL
Artemether-lumefantrine	50uM	Flunisolide	100μg/mL
Doxycycline hyclate	50uM	Budesonide	0.64nmol/ L
Quinine	150uM	Fluticasone	0.3ng/mL
Lamivudine	1 mg/mL	Lopinavir	6μg/mL
Ribavirin	1 mg/mL	Ritonavir	8.2mg/mL
Daclatasvir	1 mg/mL	Abidor	417.8ng/mL
Acetaminophen	150uM	Pooled human nasal wash	N/A

4. Cross-reactivity

Virus/Bacteria/Parasite	Strain	Source/Specimen type	Concentration	Result
SARS-coronavirus	N/A	SINO/recombinant protein	25ug/mL	Negative
MERS-coronavirus	N/A	SINO/recombinant protein	72 ug/mL	Negative
Adenovirus	Type 1	AMMS / Inactivated culturevirus	1.5E+06$TCID_{50}$/mL	Negative
	Type 3	AMMS / Inactivated culture virus	7.5E+06$TCID_{50}$/mL	Negative
	Type 5	AMMS / Inactivated culture virus	4.5E+06$TCID_{50}$/mL	Negative
	Type 7	AMMS / Inactivated culture virus	1.0E+06$TCID_{50}$/mL	Negative
	Type 8	AMMS / Inactivated culture virus	1.0E+06$TCID_{50}$/mL	Negative
	Type 11	AMMS / Inactivated culture virus	2.5E+06$TCID_{50}$/mL	Negative
	Type 18	AMMS / Inactivated culture virus	2.5E+06$TCID_{50}$/mL	Negative
	Type 23	AMMS / Inactivated culture virus	6.0E+06$TCID_{50}$/mL	Negative
	Type 55	AMMS / Inactivated culture virus	1.5E+06$TCID_{50}$/mL	Negative
Influenza A	H1N1 Denver	AMMS / Inactivated culture virus	3.0E+08$TCID_{50}$/mL	Negative
	H1N1 WS/33	AMMS / Inactivated culture virus	2.0E+08$TCID_{50}$/mL	Negative
	H1N1 A/Mal/302/54	AMMS / Inactivated culture virus	1.5E+08$TCID_{50}$/mL	Negative
	H1N1 New Caledonia	AMMS / Inactivated culture virus	7.6E+08$TCID_{50}$/mL	Negative
	H3N2 A/Hong Kong/8/68	AMMS / Inactivated culture virus	4.6E+08$TCID_{50}$/mL	Negative
Influenza B	Nevada/03/2011	AMMS / Inactivated culture virus	1.5E+08$TCID_{50}$/mL	Negative
	B/Lee/40	AMMS / Inactivated culture virus	8.5E+08$TCID_{50}$/mL	Negative
	B/Taiwan/2/62	AMMS / Inactivated culture virus	4.0E+08$TCID_{50}$/mL	Negative
Respiratory syncytial virus	N/A	AMMS / Inactivated culture virus	2.5E+06$TCID_{50}$/mL	Negative
Legionella pneumophila	Bloomington-2	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
	Los Angeles-1	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
	82A3105	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
Mycobacterium tuberculosis	K	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
	Erdman		1×10^5 PFU/mL	Negative
	HN878		1×10^5 PFU/mL	Negative
	CDC1551		1×10^5 PFU/mL	Negative
	H37Rv		1×10^5 PFU/mL	Negative
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
	178 [Poland 23F-16]	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
	262 [CIP 104340]	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
	Slovakia 14-10 [29055]	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
Streptococcus pyrogens	Typing strain T1[NCIB 11841, SF 130]	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
Mycoplasma pneumoniae	Mutant 22	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
	FH strain of E aton Agent [NCTC10119]	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
	36M129-B7	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
Coronavirus	229E	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative
	OC43	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative
	NL63	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative
	HKU1		1.5E+06TCID50/mL	Negative
Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative
Human Metapneumovirus	IA10-2003	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative
(hMPV) 16 Type A1	Type 1	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative
	Type 2	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative
	Type 3	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative
	Type 4A	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative
RhinoVIRUS A16	N/A	AMMS / Inactivated culture virus	1.5E+06TCID50/mL	Negative

ATTENTION

1. For in vitro diagnostic use only.
2. Proper specimen collection storage and transit are critical to the performance of this test.
3. Use only once.
4. Do not touch the reaction area of test strip.
5. Do not use test kit beyond the expiration date.
6. Do not use the kit if the pouch is punctured or sealed not well.
7. Testing should be applied by professionally trained staff working in certified laboratories or clinics.
8. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
9. Dispose of test cards and items in contact with samples as medical waste after use.
10. Do not freeze.

INTERPRETATION OF ICONS

	Do not re-use		Temperature limit
IVD	In vitro diagnostics medical device	LOT	Batch code
	Contains sufficient for <n>test		Consult instructions for use
	Manufacturer		Date of manufacture
CE	CE mark		Use-by date
	Keep dry		This way up
	Fragile, handle with care		Stacking layer limit
EC REP	Authorized representative in the European Community		

GENERAL INFORMATION

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