CONTIPHARMA
a member of Bedelco group

COVID19

SARS-CoV-2 Antigen Test kit

Colloidal Gold Chromatographic Immunoassay

Component	Quantity	Contain	Weight	Dimension (mm)
Test card	25 packs	Test card x 25 pcs Desiccant x 25 pcs	300g	200x115x80
Extraction tube	1 pack	Extraction tube x 25 pcs		
Nozzle cap	2 packs	Nozzle cap x 25 pcs		
Swab	25 packs	Nasopharyngeal swab x 25 pcs		
Extraction	1 bottle	Extraction buffer x 8ml		
Instruction for use	1 copy	1 copy		

PRODUCT NAME

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

SPECIFICATION

Ref. No.	Amount	Test cassette	Swab	Extraction buffer	Extraction tube
SC0232	1 T/Kit	1 pc	1 pc	1 x 0.4mL/vial	1 pc
SC0233	2 T/Kit	2 pcs	2 pcs	2 x 0.4mL/vial	2 pcs
SC0234	5 T/Kit	5 pcs	5 pcs	5 x 0.4mL/vial	5 pcs

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 swab 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. The test offers individuals the opportunity to take the nasal swab themselves under the supervision of a medical specialist.

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.

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.

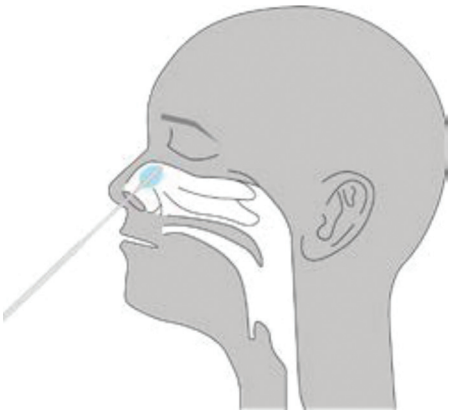
STORAGE CONDITION

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 nasal 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 nasal swabs, insert the swab into one nostril of the patient. The swab tip should be inserted 2 to 4 cm deep, until a resistance can be felt. Then roll the swab 5 times over the mucous membrane inside the nostril to ensure that both mucus and cells are collected. Repeat this step with the same cotton swab in the other nostril so that sufficient sample is collected from both nostrils. Finally withdraw the swab from the nasal cavity.



REQUIREMENTS OF SPECIMENS

1. Remove the cap of an extraction buffer, add all the extraction buffer into the extraction tube.
2. 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.

The extracted samples can be stored for no more than 1 hour at room temperature and for no more than 4 hours at a temperature in the range of 2 to 8 °C.

TEST PROCEDURE

1. Take out the test card from the aluminum foil bag and lay it flat on the test bench.
2. Add 3 drops (approximately 80µl) 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°C.humidity 35%~85%.

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.

Positive Négative Invalid

INSTRUCTIONS FOR ACTION ACCORDING TO TEST RESULT

1. In the event of a positive test result:
   - There is currently a suspicion of COVID-19 infection
   - Immediately contact a doctor/family doctor or the local health authority
   - Comply with local self-insulation guidelines
   - to have a PCR confirmation test carried out

2. In case of a negative test result:
   - Continue to comply with all applicable rules regarding contact with others and protective measures.
   - An infection may be present even if the test is negative.
   - In case of suspicion, repeat the test after 1 - 2 days, as the coronavirus cannot be detected accurately in all phases of an infection.

3. In case of an invalid test result:
   - Possibly caused by faulty test execution
   - Repeat the test
   - If test results remain invalid, contact a doctor or COVID 19 test center.

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

Nasal swab specimens from 226 patients, which included 107 COVID-19 positive and 119 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		SUM
SRAS-CoV-2 Antigen Test Kit	Result	Positive	Negative	
	Positive	102	1	103
	Negative	5	118	123
SUM		107	119	226
Sensitivity		95.33% (95%CI:91.31%~96.20%)		
Sensitivity		99.16% (95%CI:95.39%~99.85%)		
Accuracy		97.35% (95%CI:95.37%~97.74%)		

2. LIMIT OF DETECTION (LOD)

2019-nCoV Concentration	1 X 106 $TCID_{50}$/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	$6.25X10^2TCID_{50}$/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	100µg/mL
Oseltamivir	Hydrochloride	100µg/mL	1mmol/mL
Artemether-lumefantrine	10 mg/mL	Peramivir	100µg/mL
Doxycycline hyclate	50uM	Flunisolide	0.64nmol/ L
Quinine	50uM	Budesonide	0.3ng/mL
Lamivudine	150uM	Fluticasone	6µg/mL
Ribavirin	1 mg/mL	Lopinavir	8.2mg/mL
Daclatasvir	1 mg/mL	Ritonavir	417.8ng/mL
Acetaminophen	1 mg/mL	Abidor	N/A

4. CROSS-REACTIVITY

Virus/Bacteria/ Parasite	Strain	Source/Specimen type	Concentration	Result
SRAS-coronavirus	N/A	SINO/recombinant protein	25ug/mL	Negative
MERS-coronavirus	N/A		72 ug/mL	Negative
Adenovirus	Type 1	AMMS Inactivated culture virus	1,5E+06TCID$_{50}$/mL	Negative
	Type 3		7,5E+06TCID$_{50}$/mL	Negative
	Type 5		4,5E+06TCID$_{50}$/mL	Negative
	Type 7		1,0E+06TCID$_{50}$/mL	Negative
	Type 8		1,0E+06TCID$_{50}$/mL	Negative
	Type 11		2,5E+06TCID$_{50}$/mL	Negative
	Type 18		2,5E+06TCID$_{50}$/mL	Negative
	Type 23		6,0E+06TCID$_{50}$/mL	Negative
	Type 55		1,5E+06TCID$_{50}$/mL	Negative
Influenza A	H1N1 Denver	AMMS / Inactivated culture virus	3,0E+08TCID$_{50}$/mL	Negative
	H1N1 WS/33		2,0E+08TCID$_{50}$/mL	Negative
	H1N1 A/Mal/302/54		1,5E+08TCID$_{50}$/mL	Negative
	H1N1 New Caledonia		7,6E+08TCID$_{50}$/mL	Negative
	H3N2 A/ Hong Kong/8/68		4,6E+08TCID$_{50}$/mL	Negative

Virus/Bacteria/ Parasite	Strain	Source/Specimen type	Concentration	Result
Influenza B	Nevada/03/2011	AMMS / Inactivated culture virus	1,5E+08TCID$_{50}$/mL	Negative
	B/Lee/40		8,5E+08TCID$_{50}$/mL	Negative
	B/Taiwan/2/62		4,0E+08TCID$_{50}$/mL	Negative
Virus respiratoire syncytial	N/A	AMMS / Inactivated culture virus	2,5E+06TCID$_{50}$/mL	Negative
Legionella pneumophila	Bloomington-2	AMMS / Inactivated culture virus	1×10^5 PFU/mL	Negative
	Los Angeles-1		1×10^5 PFU/mL	Negative
	82A3105		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]		1×10^5 PFU/mL	Negative
	262 [CIP 104340]		1×10^5 PFU/mL	Negative
	Slovakia 14-10 [29055]		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]		1×10^5 PFU/mL	Negative
	36M129-B7		1×10^5 PFU/mL	Negative
Coronavirus	229E	AMMS / Inactivated culture virus	1,5E+06TCID$_{50}$/mL	Negative
	OC43		1,5E+06TCID$_{50}$/mL	Negative
	NL63		1,5E+06TCID$_{50}$/mL	Negative
	HKU1		1,5E+06TCID$_{50}$/mL	Negative
Human etapneumovirus 3 Type B1	Peru2-2002	AMMS / Inactivated culture virus	1,5E+06TCID$_{50}$/mL	Negative
Human Metapneumovirus	IA10-2003	AMMS / Inactivated culture virus	1,5E+06TCID$_{50}$/mL	Negative
(hMPV) 16 Type A1	Type 1	AMMS / Inactivated culture virus	1,5E+06TCID$_{50}$/mL	Negative
	Type 2		1,5E+06TCID$_{50}$/mL	Negative
	Type 3		1,5E+06TCID$_{50}$/mL	Negative
	Type 4A		1,5E+06TCID$_{50}$/mL	Negative
RhinoVIRUS A16	N/A	AMMS / Inactivated culture virus	1,5E+06TCID$_{50}$/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 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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