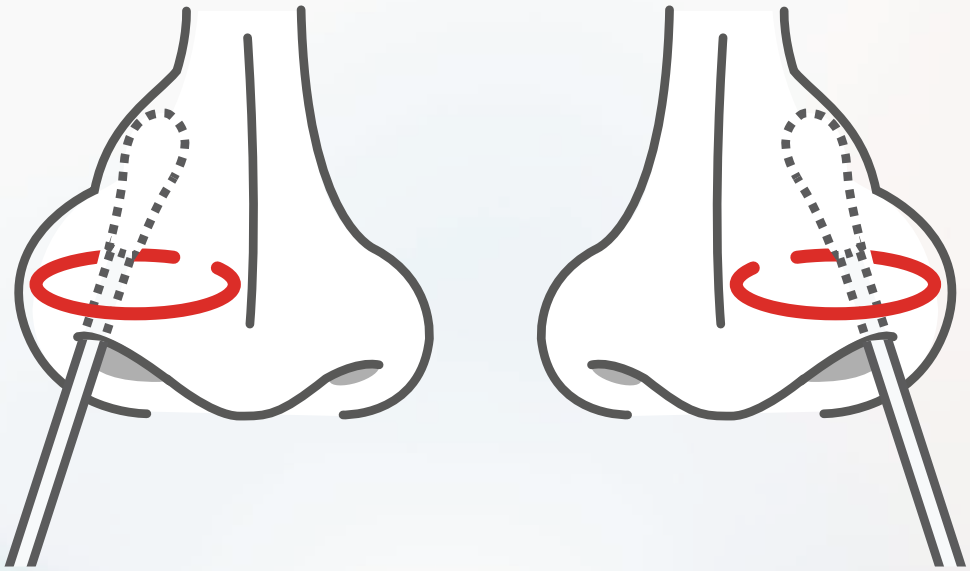
Hotgen

Stock Code 688068.SH



Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Product Features

- High Accuracy, Specificity and Sensitivity
- No need instrument, get results in 15 minutes
- Room temperature storage
- Sample : Human Anterior Nares Swab
- Detect the presence of viral proteins
- Identify acute or early infection

CE

Clinical Performance

(Disease Course 5-7 Days)

Sensitivity: 96.30%; Specificity: 99.13% ; Accuracy: 97.76%.

Novel Coronavirus 2019-nCoV Antigen Test(Colloidal Gold)

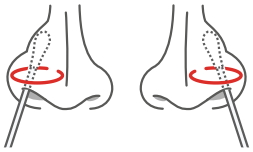
Specimen Requirements

① Sample collection

Gently insert the entire soft tip of the swab into one nostril for 1.5cm until you feel a bit of resistance.

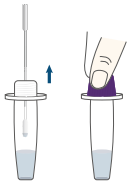
Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 4 times for a total time of 15 seconds.

Repeat the same process with the same swab in the other nostril.



② Sample treatment

The swab after sampling is soaked below the liquid level of the sample extraction buffer. Rotate and press 3 times. The swab soaking time is not less than 15s.



The swab head is pressed, then take out the swab and tighten the sampling tube.

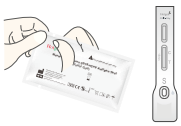
③ Sample preservation

The treated sample should be tested within 1h.

Test Procedure

① 

Place the test cassette, sample extraction buffer at room temperature for 15~30 minutes, and equilibrate to room temperature (10~30℃).

② 

Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.

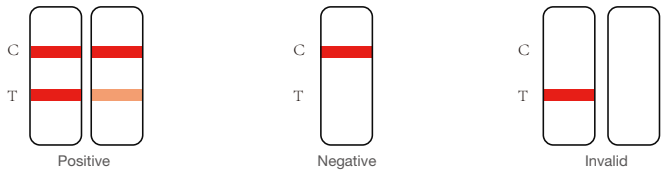
③ 

Add 4 drops of the treated sample into the sample well of the test cassette. (In case of chromato-graphic abnormalities, extra add 1~2 drops of the treated sample accordingly.) Incubate at 10~30℃ for 15 minutes.

④ 

Observe the results after Incubate at 10~30℃ for 15 minutes. The result after 30 minutes is invalid.

Interpretation of result



Clinical Performance

This study enrolled a total of 223 human anterior nasal swab specimens, of which 108 were positives for RT-PCR Test, 115 negatives for RT-PCR Test; As for data collection of the corresponding RT-PCR Test results.

Assessment system Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Reference system (clinical diagnostic results)		
	Positive(+)	Negative(-)	Total
Positive(+)	104	1	105
Negative(-)	4	114	118
Total	108	115	223

Sensitivity: 96.30%; Specificity: 99.13 %; Accuracy: 97.76%.

Product information

Product name	Test samples	Specifications	Storage conditions
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Human Anterior Nares Swab	1T/kit, 5T/kit, 20T/kit, 40T/kit	4-30℃

Beijing Hotgen Biotech Co.,Ltd

Add.: 9 building, No.9 Tianfu Street, Daxing District, Beijing, 102600, P.R. China

Website: www.hotgen.com.cn

Company Profile

Beijing Hotgen Biotech Co., Ltd. (abbreviated as Hotgen Biotech, stock code: 688068) was established in June 2005, which is a high-tech enterprise focusing on the research& development, manufacture and sales of medical and public safety inspection products of in vitro diagnostics (IVD) in the field of biomedicine, as well as landed on the China Sci-Tech innovation board (STAR Market) in September 2019.

After serval years of Research& development, Hotgen Biotech has developed an in vitro diagnostic reagent bioactive raw material development platform, a sugar chain abnormal protein detection (sugar capture) R&D technology platform, a Magnetic particles chemiluminescence R&D technology platform, a Up-converting Phosphor R&D technology platform, and a colloidal gold immune layer, The eight major technology platforms, such as the precipitation R&D platform, enzyme-linked immunoassay R&D technology platform, molecular diagnostics R&D platform, and instrument R&D technology platform, form a closed-loop system for in vitro diagnostic R&D and production. Hotgen Biotech has established a complete full level immunodiagnostic technology platform, from high-precision Up-converting Phosphor POCT (UPT series) to small, medium and large single- cartridge chemiluminescence platforms (MQ60 series), and then to large-scale full-automatic chemiluminescence Platform (C2000), which realizes the application of the immune diagnostic platform in the field of full diagnostic scenarios. Supporting products are widely used in the clinical and public safety fields. Specific users include hospitals at all levels, township health centers, third-party testing centers, and medical institutions, as well as medical and health institutions, as well as disease control centers, public security, fire protection, military, ports, food and medicine. Supervision, food and feed enterprises and other public safety fields.

Hotgen Biotech has won the second prize of the National Technology Invention Award, the Gold Medal of Independent Innovation, and the second prize of the Chinese Medical Science and Technology Award; In 2018, Hotgen Biotech was awarded the second prize of the "Technical Invention Category of China Rare Earth Science and Technology Award" by the China Rare Earth Society; Top 100 Private Scientific and Technological Innovations "and" Top 100 Medical Enterprises of the Future "; and" Postdoctoral Scientific Research Workstation "; major science and technology projects in the 12th and 13th five years, 863 plan, science and technology projects of the Beijing Science and Technology Commission, and Zhongguancun High Precision The project's major cutting-edge original technological achievements transformation and industrialization projects.

In the face of the COVID-19 epidemic situation, Beijing Hotgen Biotech Co.,Ltd has organized R&D developed a variety of Covid-19 detection reagents, including Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold), Novel Coronavirus 2019-nCoV Antigen Test (Up-converting Phosphor Immunochromatographic Technology), Coronavirus disease(COVID-19) Antibody Test (Colloidal Gold), Coronavirus disease(COVID-19) IgM/IgG Antibody Rapid Test（Colloidal Gold), Novel Coronavirus 2019-nCoV Antibody Test (Up-converting Phosphor Immunochromatographic Technology), Novel Coronavirus (SARS-CoV-2) Neutralizing Antibodies Test (Colloidal Gold), Coronavirus disease(COVID-19) Nucleic Acid Test Kit (PCR-Fluorescent Probe Method), Disposable virus sampling tube, Nucleic acid Automatic Purification System, Nucleic acid extraction reagent, Biological Sample Releaser kit, etc.It is imperative to fight the epidemic Helping the global fight against epidemics!

Since its establishment, the company has continuously grown its business and has now achieved group development. At present, Hotgen (Langfang), Hotgen (Jilin), Weikekang Technology, Shunjing Biological and many other subsidiaries have been established. Hotgen Biotech marketing and service network has covered all regions of the country. Each province is equipped with professional technical service engineers, academic engineers, etc. who are responsible for pre-sales and after-sales work to meet customer needs. The company takes "developing biotechnology and benefiting human health" as its mission, "quality determines the company's life and death, customers determine the company's success or failure, talents determine the company's rise and fall, innovation determines the company's future" as its core values, and "tests because of me advanced" as its philosophy , High ambitions, technological entrepreneurship, and industrial prosperity!

gold color reaction of T line and C line to determine results of SARS-CoV-2 antigen in human anterior nasal swab samples.

STORAGE AND SHELF LIFE

1. The kit should be stored at 4~ 30℃, the shelf life is set for 18 months.
2. After the foil bag is opened, it should be used within 30 minutes (temperature 10~30℃, humidity ≤70%).
3. The sample extraction buffer should be used within 18 months after opening (temperature 10~30℃, humidity ≤70%).

See label for manufacture date and expiration date.

LIMITATIONS

1. The test result of this kit is not the only confirmation indicator of clinical indications. The infection should be confirmed by a specialist along with other laboratory results, clinical symptoms, epidemiology, and additional clinical data.·
2. In the early stages of infection, low levels of antigen expression can result in negative results.
3. The sample test results are related to the quality of sample collection, processing, transportation and storage. Any errors may lead to inaccurate results. If cross-contamination is not controlled during sample processing, false positive results may occur.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection (LoD)

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) has been confirmed can detect SARS-CoV-2 at 2.5 × $10^{2.2}$ $TCID_{50}$/mL, which was collected from a confirmed COVID-19 patient in China.

2. Study on Exogenous/Endogenous Interference Substances:

The potential interfering substances listed below do not interfere.

(1) Exogenous factor

No.	Exogenous factor	Interfering substances	Test conc.
1	Nasal sprays or drops	Phenylephrine	128μg/mL
2		Oxymetazoline	128μg/mL
3		Saline Nasal Spray 10%	10%(v/v)
4	Nasal corticosteroids	Dexamethasone	2μg/mL
5		Flunisolide	0.2μg/mL
6		Triamcinolone acetonide	0.2μg/mL
7		Mometasone	0.5μg/mL
8	Throat lozenges	Strepsils (flurbiprofen 8.75mg)	5% (w/v, 50mg/mL)
9		Throat candy	5% (w/v, 50mg/mL)
10	Oral anaesthetic	Anbesol (Benzocaine 20%)	5% (v/v)
11	Anti-viral drugs	α-Interferon-2b	0.01μg/mL
12		Zanamivir (Influenza)	2μg/mL
13		Ribavirin (HCV)	0.2μg/mL
14		Oseltamivir (Influenza)	2μg/mL
15		Peramivir(Influenza)	60μg/mL
16		Lopinavir(HIV)	80μg/mL
17		Ritonavir(HIV)	20μg/mL
18		Arbidol((Influenza)	40μg/mL
19	Antibiotic	Levofloxacin Tablets	40μg/mL
20		Azithromycin	200μg/mL
21		Ceftriaxone	800μg/mL
22		Meropenem	100μg/mL
23	Antibacterial, systemic	Tobramycin	128μg/mL
24	Other	Mucin: bovine submaxillary gland, type	100 μg/mL
25		Biotin	100 μg/mL

(2) Endogenous factor

No.	Endogenous factor	Interfering substances	Test conc.
1	Autoimmune disease	Human anti-mouse antibody, HAMA	800 ng/mL
2	Serum protein	Whole Blood (human), EDTA anticoagulated	10% (w/w)

3. Cross-Reactivity & Microbial interference:

There is no cross-reaction and no interference with the potentially cross-reactive microorganisms listed below.

No.	Crossing reacting substance	Strain	Concentration of cross reacting substance
1	Human Coronavirus	HKU1	2 × 10^5 $TCID_{50}$/mL
2		229E	2 × 10^5 $TCID_{50}$/mL
3		OC43	2 × 10^5 $TCID_{50}$/mL
4		NL63	2 × 10^5 $TCID_{50}$/mL
5		SARS	2 × 10^5 $TCID_{50}$/mL
6		MERS	2 × 10^5 $TCID_{50}$/mL
7	Adenovirus	Type 1	2 × 10^5 $TCID_{50}$/mL
8		Type 2	2 × 10^5 $TCID_{50}$/mL
9		Type 3	2 × 10^5 $TCID_{50}$/mL
10		Type 4	2 × 10^5 $TCID_{50}$/mL
11		Type 5	2 × 10^5 $TCID_{50}$/mL
12		Type 7	2 × 10^5 $TCID_{50}$/mL
13		Type 55	2 × 10^5 $TCID_{50}$/mL
14	Human Metapneumovirus (hMPV)	hMPV 3 Type B1 / Peru2-2002	2 × 10^5 $TCID_{50}$/mL
15		hMPV 16 Type A1 / IA10-2003	2 × 10^5 $TCID_{50}$/mL
16	Parainfluenza virus	Type 1	2 × 10^5 $TCID_{50}$/mL
17		Type 2	2 × 10^5 $TCID_{50}$/mL
18		Type 3	2 × 10^5 $TCID_{50}$/mL
19		Type 4A	2 × 10^5 $TCID_{50}$/mL
20	Influenza A	H1N1	2 × 10^5 $TCID_{50}$/mL
21		H3N2	2 × 10^5 $TCID_{50}$/mL
22		H5N1	2 × 10^5 $TCID_{50}$/mL
23		H7N9	2 × 10^5 $TCID_{50}$/mL
24	Influenza B	Yamagata	2 × 10^5 $TCID_{50}$/mL
25		Victoria	2 × 10^5 $TCID_{50}$/mL
26	Enterovirus	Type 68	2 × 10^5 $TCID_{50}$/mL
27		09/2014 isolate 4	2 × 10^5 $TCID_{50}$/mL
28	Respiratory syncytial virus	Type A	2 × 10^5 $TCID_{50}$/mL
29		Type B	2 × 10^5 $TCID_{50}$/mL
30	Rhinovirus	A16	2 × 10^5 $TCID_{50}$/mL
31		Type B42	2 × 10^5 $TCID_{50}$/mL
32	Chlamydia pneumoniae	TWAR strain TW-183	5 × 10^6 CFU/mL
33	Haemophilus influenzae	NCTC 4560	5 × 10^6 CFU/mL
34	Legionella pneumophila	Bloomington-2	5 × 10^6 CFU/mL
35		Los Angeles-1	5 × 10^6 CFU/mL
36		82A3105	5 × 10^6 CFU/mL
37	Mycobacterium tuberculosis	K	5 × 10^6 CFU/mL
38		Erdman	5 × 10^6 CFU/mL
39		HN878	5 × 10^6 CFU/mL
40		CDC1551	5 × 10^6 CFU/mL
41		H37Rv	5 × 10^6 CFU/mL
42	Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	5 × 10^6 CFU/mL
43		178 [Poland 23F-16]	5 × 10^6 CFU/mL
44		262 [CIP 104340]	5 × 10^6 CFU/mL
45		Slovakia 14-10 [29055]	5 × 10^6 CFU/mL
46	Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF 130]	5 × 10^6 CFU/mL
47	Bordetela pertussis	NCCP 13671	5 × 10^6 CFU/mL
48	Mycoplasma	Mutant 22	5 × 10^6 CFU/mL
49	pneumoniae	FH strain of Eaton Agent [NCTC 10119]	5 × 10^6 CFU/mL
50		M129-B7	5 × 10^6 CFU/mL
51	Pneumocystis jirovecii (PJP)	N/A	N/A
52	Pooled human nasal wash	N/A	N/A
53	Candida albicans	3147	5 × 10^6 CFU/mL
54	Pseudomonas aeruginosa	R. Hugh 813	5 × 10^6 CFU/mL
55	Staphylococcus epidermidis	FDA strain PCI 1200	5 × 10^6 CFU/mL
56	Streptococcus salivarius	S21B [IFO 13956]	5 × 10^6 CFU/mL

4. Hook Effect:

There is no hook effect at 1.0 × $10^{6.2}$ $TCID_{50}$/mL of SARS-CoV-2 isolated from a SARS-CoV-2 confirmed patient in China.

5. Clinical Performance:

Clinical performance of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) has been determined by testing 108 positive and 115 negative specimens for SARS-CoV-2 antigen (Ag). The sensitivity is 96.30% (95% CI: 90.79-98.98%), and the specificity is 99.13% (95% CI: 95.25-99.98%).

		PCR Test Results		
		Positive	Negative	Total
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Results	Positive	104	1	105
	Negative	4	114	118
	Total	108	115	223
		Sensitivity	Specificity	Overall Percentage Agreement
		96.30% [90.79%;98.98%]	99.13% [95.25%;99.98%]	97.76% [94.85%;99.27%]

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Please read this instruction carefully before the test.
2. Please use the swab and sample extraction buffer provided in this kit, and do not replace the sample extract in this kit with components in other kits.
3. Operations should strictly follow the instructions.
4. Positive and negative predictive values are highly dependent on the prevalence. When the prevalence of the disease is low and SARS-CoV-2 has little/no activity, a positive test results is more likely to represent a false positive result; when the prevalence of the disease is high, false negative test results are more likely.
5. Compared with a RT-PCR SARS-CoV-2 assay, this test is less sensitive when used to detect patient samples within the first five days of the onset of symptoms.
6. The test cassette must be used within 30 minutes after opening (temperature 10~30℃, humidity ≤70%), it should be used immediately after opening at 30℃, and the unused test cassette must be sealed and dryly stored.
7. Waste or excess samples produced during testing should be inactivated according to regulations on infectious agents.

EXPLANATION FOR IDENTIFICATION

	Use by date	LOT	Batch		Consult Instruction for use
Σ	Content Sufficient For <n> Tests		Temperature limitation	REF	Catalog Number
	Manufacturing date		Caution		Do not reuse

CE	CE Marking – IVDD 98/79/EC	EC REP	Authorized representative in the European Community		Manufacturer
IVD	For In Vitro Diagnostic Use		Keep away from sunlight		Keep dry
	For self-testing	/	/	/	/

Beijing Hotgen Biotech Co., Ltd.
9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District, Beijing, 102600, P.R. China.

EC REP MedNet GmbH
Borkstrasse 10, 48163 Muenster, Germany

IVD

APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION

Approved on February, 2021;

Version number: V. 2021-02.01[Eng.]