Hotgen

Stock Code： 688068.SH

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Summary Data

Beijing Hotgen Biotech Co., Ltd.

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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 : Nasopharyngeal Swab , Throat Swab
- Detect the presence of viral proteins
- Identify acute or early infection
- The sensitivity is 2.5×10^2 pfu/mL

Clinical Performance

(Disease Course 5-7 Days)

Sensitivity: **96.62%**; **Specificity**: **99.76%**; **Accuracy: 98.70%.**

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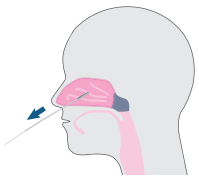
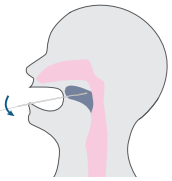
Novel Coronavirus 2019-nCoV Antigen Test(Colloidal Gold)

Sample Collection



Nasopharyngeal swab: The sampler holds the swab to enter the nostril, and when the tip of the swab reaches the back wall of the nasopharyngeal cavity, gently rotate it for a circle, and then slowly take out the swab.

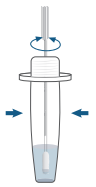
or



Throat Swab: The swab crosses the base of the tongue, and wipes the tonsils back and forth with slight force on both sides of the person being collected for at least 3 times, and then wipes up and down the posterior pharyngeal wall at least 3 times.

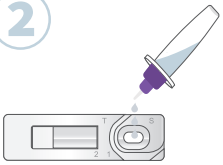
Test Procedure

1



The swab after sampling is soaked below the liquid level of the sampling tube, rotated and pressing 3 times, the swab soaking time is not less than 15s, the swab head is pressed, then taken out the swab and tighten the sampling tube. The liquid in the tube is the sample after treatment.

2

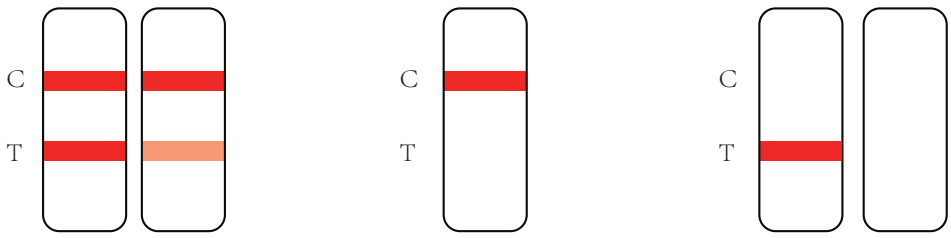


Add 4-5 drops of the treated sample into the sample well of the test cassette.

3

Observe results after 15 mintes, result got after 30 minutes is invalid.

Interpretation of result



Clinical Performance

A total of 617 nasal swab samples were tested in this test, and the results of throat swabs samples were analyzed statistically. The collecting time of patient samples is not exceding 7 days after clinical manifestations with a novel coronavirus infection in clinical institutions.

Assessment system Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Reference system (clinical diagnostic results)		
	Positive(+)	Negative(-)	Total
Positive(+)	200	1	201
Negative(-)	7	409	416
Total	207	410	617

Sensitivity: 96.62%; Specificity: 99.76%; Accuracy: 98.70%.

Product information

Product name	Test samples	Specifications	Storage conditions
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Nasopharyngeal swab , Throat 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 Wechat/WhatsApp:008618910289851

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!

Declaration of Conformity

Manufacturer:

Name: Beijing Hotgen Biotech Co.,Ltd

Address: 9th building, No.9 Tianfu Street, Biomedical Base,Daxing District, Beijing, 102600, P.R.China

European Representative:

MedNet GmbH Borkstrasse 10,48163 Muenster,Germany

Product Name:

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Novel Coronavirus 2019-nCoV Antigen Test (Up-converting Phosphor Immunochromatographic Technology)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012,EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011,EN 13612:2002,EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002,EN 13975:2003, EN 62366:2008

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Signature: Lin Changqing

Name: Lin Changqing

Title: General manager

Place: Beijing,China.

Date of Issue: Aug 27, 2020

CERTIFICATE

of EU product notification

Reference Number: JH-ERA-18041V00
Issued Date: September 10, 2020

This is certify that, according to In Vitro Diagnostic Medical Device 98/79/EC, we accepted the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

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

The Manufacturer declared that the IVD device complies with the Directive including all essential requirements. According to In Vitro Diagnostic Medical Device 98/79/EC, the European Databank on Medical Devices (EUDAMED) is established May 1, 2011, the German Competent Authority is notified of the manufacturer's In Vitro Diagnostic Medical Devices and has allocated registration numbers shown in:

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
EDMA CODE :15-04-80-90-00
Registration number :DE/CA22/419-1848-IVD

Where the manufacturer affix the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.

CE

MedNet GmbH
Borkstrasse 10,48163 Muenster,Germany

Dr. Eva Steffens
MedNet GmbH

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Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Instructions for Use

PRODUCT NAME

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

SPECIFICATIONS

1T/kit, 5T/kit, 20T/kit, 25T/kit, 40T/kit, 50T/kit.

INTENDED USE

This kit is used for in vitro qualitative determination of novel coronavirus antigen in human nasal swabs or throat swabs. It is used as rapid investigation for suspected cases of novel coronavirus, can also be used as a reconfirmation method for nucleic acid detection in discharged cases.

A positive test result indicates that the samples contained novel coronavirus antigen. A negative test result does not rule out the possibility of infection.

This product is only used for clinical and emergency reserve during the pneumonia outbreak of novel coronavirus infection, and can not be used as a routine in vitro diagnostic reagent for clinical application . The test results of this kit are for clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests.

For professional use only.

PRINCIPLE OF THE ASSAY

This kit is based on the Colloidal gold immunochromatographic technology, and uses double antibody sandwich method to detect the novel coronavirus antigen in human throat swabs or nasal swabs. The detection line (T line) of the novel coronavirus antigen test cassette was coated with novel coronavirus antibody, and the quality control line (C line) was coated with sheep anti-mouse. During the test, the sample is dropped into the test cassette and the liquid is chromatographed upward under the capillary effect. The novel coronavirus antigen in the sample first binds to the Colloidal gold-labelled novel coronavirus antibody to form a solid phase novel coronavirus antibody-novel coronavirus antigen-labelled novel coronavirus antibody-Colloidal gold complex at the T line position, and form a solid phase sheep anti-mouse-labelled novel coronavirus antibody- Colloidal gold complex was formed at the C line position. After the test is completed, observe the Colloidal gold color reaction of T line and C line to determine results of novel coronavirus antigen in nasal swabs or throat swabs.

COMPONENTS

1. Novel Coronavirus Antigen Test Cassette 2. Sample extraction buffer 3. Disposable virus sampling swab

STORAGE AND SHELF LIFE

1. The kit should be stored at 4~ 30°C, 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°C, humidity ≤70%), and it should be used immediately after opening at 30°C.
3. The sample extraction buffer should be used within 18 months after opening (temperature 10~30°C, humidity ≤70%).
4. Date of manufacture and expiration date see label.

SPECIMEN REQUIREMENTS

1. Sample collection

Nasal swab: The sampling staff hold a swab and stick into the nostril and goes back slowly along the bottom of the lower nasal canal, when the top of the swab reaches the posterior wall of the nasopharyngeal cavity, rotate gently for a cycle (if reflex cough, stay for a moment), and then slowly remove the swab.

Throat swab: Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with a little force back and forth at least 3 times. Then wipe up and down the Posterior pharyngeal wall at least 3 times .

2. Sample treatment

The swab after sampling is soaked below the liquid level of the sample extraction buffer, rotated and pressing 3 times, the swab soaking time is not less than 15s, the swab head is pressed, then taken out the swab and tighten the sampling tube. The liquid in the tube is the sample after treatment.

3. Sample preservation

The sample of treated should be tested within 1h. Specimens that can not be detected within 24 hours should be kept at -70°C or below. Repeated freezing and thawing should be avoided during specimen transportation. Specimen collection should be sent to the laboratory as soon as possible. If it is necessary to transport the specimen for a long distance, it is recommended to preserve the specimen by refrigeration such as dry ice.

TEST PROCEDURE

1. Place the test cassette, sample extraction buffer at room temperature for 15~30 minutes, and equilibrate to room temperature (10~30°C).
2. Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.
3. Write sample ID on the plastic case of the test cassette.
4. Add 4~5 drops of the treated sample into the sample well of the test cassette. Incubate at 10~30°C for 15 minutes.
5. Observe the results after Incubate at 10~30°C for 15 minutes. Result got after 30 minutes is invalid.

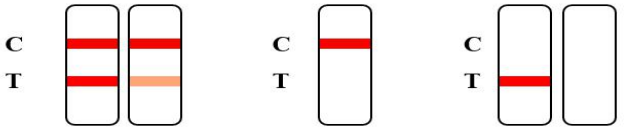
This kit doesn't have quality control products. It is recommended that the users establish a quality control method suitable for its laboratory.

INTERPRETATION OF RESULT

Positive: Two color bands appear in the observation window, that is, a red or magenta line appears at the position of the quality control line (C line) and the detection line (T line) (as shown in result 1), which indicates the test result of novel coronavirus antibody in the sample was positive.

Negative: A red or magenta line appears at the position of the quality control line (C line) in the observation window, and no line appears at the position of the test line (T line) (as shown in the result 2), indicating the test results of the novel coronavirus antibodies in the sample were negative or the concentration was below the limit of detection of the kit.

Invalid: No line appears in the position of the quality control line (line C) in the observation window (as shown in result 3), which indicates that the test is invalid, should collect sample again and retest.



Result 1: Positive **Result 2: Negative** **Result 3: Invalid**

LIMITATIONS

1. This kit is a qualitative test and cannot quantify the concentration of the novel coronavirus antigen.
2. The test result of this kit is not the only confirmation indicator of clinical indications. If the test result is not in consistent with clinical evidence, it is recommended to conduct supplementary tests to verify the result.
3. Sample test results are related to the quality of sample collection, processing, transportation and storage. Any errors may cause inaccurate test results. If cross-contamination is not controlled during sample processing, false positive results may occur.

PERFORMANCE CHARACTERISTICS

1. When testing with enterprise references, meet the following standards:

1.1 Negative references compliance rate: Use the enterprise negative references for testing, and the negative references should be detected at least 20/20 (-/-).

1.2 Positive references compliance rate: Use the enterprise positive references for testing, and the positive references should be detected at least 5/5 (+ / +).

1.3 Sensitivity references: When using enterprise sensitivity references for detection, at least 1/3 (+ / +) should be detected.

1.4 Repeatability: Use enterprise precision references for testing, and the test results of repeatable references should be consistent.

2. Limit of Detection (LoD)

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) was confirmed to detect $2.5\times10^{2.2}$ $TCID_{50}$/mL of SARS-CoV-2 which was collected from a COVID-19 confirmed patient in China.

3. Exogenous/Endogenous Interference Substances studies:

There was no interference for potential interfering substances listed below.

(1) Exogenous factor

No.	Exogenous factor	Interfering substances	Test conc.
1	Nasal sprays	Phenylephrine	128μg/mL
2	or drops	Oxymetazoline	128μg/mL
3		Saline Nasal Spray 10%	10%(v/v)
5	Nasal corticosteroids	Dexamethasone	2μg/mL
6		Flunisolide	0.2μg/mL
7		Triamcinolone acetonide	0.2μg/mL
8		Mometasone	0.5μg/mL
9	Throat lozenges	Strepsils (flurbiprofen 8.75mg)	5% (w/v, 50mg/mL)
10		Throat candy	5% (w/v, 50mg/mL)
11	Oral anaesthetic	Anbesol (Benzocaine 20%)	5% (v/v)
12	Anti-viral drugs	α-Interferon-2b	0.01μg/mL
13		Zanamivir (Influenza)	2μg/mL
14		Ribavirin (HCV)	0.2μg/mL
15		Oseltamivir (Influenza)	2μg/mL
16		Peramivir(Influenza)	60μg/mL
17		Lopinavir(HIV)	80μg/mL
18		Ritonavir(HIV)	20μg/mL
19		Arbidol((Influenza)	40μg/mL
20	Antibiotic	Levofloxacin Tablets	40μg/mL
21		Azithromycin	200μg/mL
22		Ceftriaxone	800μg/mL
23		Meropenem	100μg/mL
24	Antibacterial, systemic	Tobramycin	128μg/mL
25	Other	Mucin: bovine submaxillary gland, type	100 μg/mL
26		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)

4. Cross-Reactivity & Microbial interference:

There was no cross-reaction and interference with the potential cross-reacting microorganisms listed below.

No.	Crossing reacting substance	Strain	Concentration of cross reacting substance
1	Human Coronavirus	HKU1	2×10^5 TCID50/mL
2		229E	2×10^5 TCID50/mL
3		OC43	2×10^5 TCID50/mL
4		NL63	2×10^5 TCID50/mL
5		SARS	2×10^5 TCID50/mL
6		MERS	2×10^5 TCID50/mL
7	Adenovirus	Type 1	2×10^5 TCID50/mL
8		Type 2	2×10^5 TCID50/mL
9		Type 3	2×10^5 TCID50/mL
10		Type 4	2×10^5 TCID50/mL
11		Type 5	2×10^5 TCID50/mL
12		Type 7	2×10^5 TCID50/mL
13		Type 55	2×10^5 TCID50/mL

14	Human Metapneumovirus (hMPV)	hMPV 3 Type B1 / Peru2-2002	2×10^5 TCID50/mL
15		hMPV 16 Type A1 / IA10-2003	2×10^5 TCID50/mL
16	Parainfluenza virus	Type 1	2×10^5 TCID50/mL
17		Type 2	2×10^5 TCID50/mL
18		Type 3	2×10^5 TCID50/mL
19		Type 4A	2×10^5 TCID50/mL
20	Influenza A	H1N1	2×10^5 TCID50/mL
21		H3N2	2×10^5 TCID50/mL
22		H5N1	2×10^5 TCID50/mL
23		H7N9	2×10^5 TCID50/mL
24	Influenza B	Yamagata	2×10^5 TCID50/mL
25		Victoria	2×10^5 TCID50/mL
26	Enterovirus	Type 68	2×10^5 TCID50/mL
27		09/2014 isolate 4	2×10^5 TCID50/mL
28	Respiratory syncytial virus	Type A	2×10^5 TCID50/mL
29		Type B	2×10^5 TCID50/mL
30	Rhinovirus	A16	2×10^5 TCID50/mL
31		Type B42	2×10^5 TCID50/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 pneumoniae	Mutant 22	5×10^6 CFU/mL
49		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

5. Hook Effect:

There is no hook effect at $1.0 \times 10^{6.2}$ $TCID_{50}$/mL of SARS- CoV-2 which was isolated from a COVID-19 confirmed patient in China.

6. Clinical Performance:

(1) Nasal swab samples

Clinical performance of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) was determined by testing 207 positive and 410 negative specimens for SARS-CoV-2 antigen (Ag) to have a sensitivity of 96.62% (95% CI: 93.16-98.63%) and specificity of 99.76% (95% CI: 98.65-99.99%).

		PCR Test Results		
		Positive	Negative	Total
Novel Coronavirus 2019-CoV Antigen Test (Colloidal Gold) Results	Positive	200	1	201
	Negative	7	409	416
	Total	207	410	617
		Sensitivity	Specificity	Overall Peccentage Agreement
		96.62% [93,16%;98,63%]	99.76% [98,65%;99,99%]	98.70% [97,46%;99,44%]

(2) Throat swab samples

Clinical performance of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) was determined by testing 207 positive and 410 negative specimens for SARS-CoV-2 antigen (Ag) to have a sensitivity of 97.10% (95% CI: 93.80-98.93%) and specificity of 99.76% (95% CI: 98.65-99.99%).

		PCR Test Results		
		Positive	Negative	Total
Novel Coronavirus 2019-CoV Antigen Test (Colloidal Gold) Results	Positive	201	1	202
	Negative	6	409	415
	Total	207	410	617
		Sensitivity	Specificity	Overall Percentage Agreement
		97.10% [93.80%;98.93%]	99.76% [98.65%;99.99%]	99.01% [97.97%;99.60%]

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Please read this instruction carefully before experiment.
2. Please use the swab and sample extraction buffer provided by this kit, Do not replace the sample extract in this kit with components in other kits.
3. Operation should be strictly performed according to the instruction, and different batches should not be mixed use.
4. The user should test the specimen as soon as possible, and the clinical performance evaluation of frozen sample may be different from that of fresh sample.
5. Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
6. Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.
7. 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.
8. Waste or excess samples produced during testing should be inactivated according to 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

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

EC REP MedNet GmbH
Borkstrasse 10, 48163 Muenster, Germany

Swab:

CE 0123

Zhejiang Gongdong Medical Technology Co., Ltd.
No.10 Beiyuan Ave., Huangyan, Taizhou City, 318020 Zhejiang, China

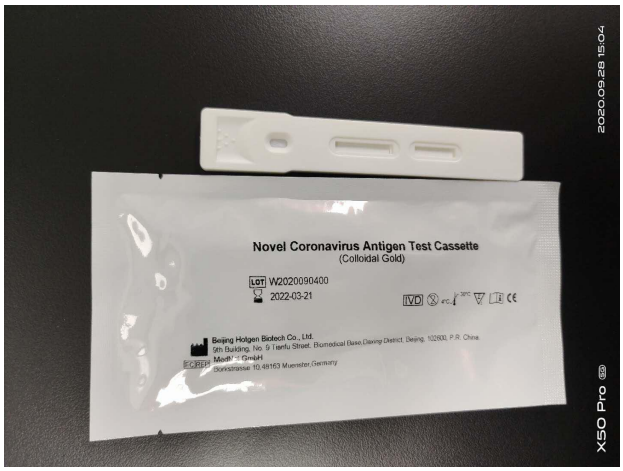
EC REP Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

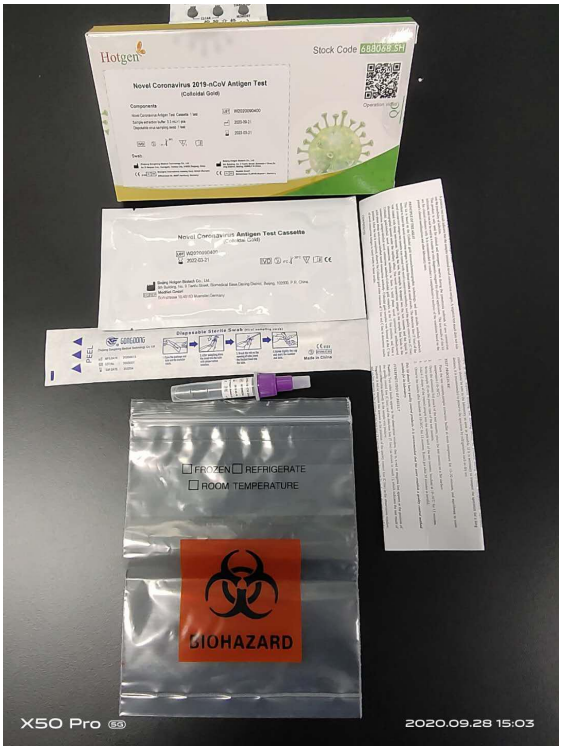
IVD

APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION

Approved on Nov., 2020;
Verision number:V. 2020-11.01[Eng.]

Product Photos





抗原胶体金检测试剂包装信息

Novel Coronavirus 2019-nCoV Antigen Test(Colloidal Gold)

（Colloidal Gold）

Packing Information

产品名称 **Product name**	规格/盒 **Specifications**	单位 **Unit**	单位包装毛重 **Gross weight per unit package**
Novel Coronavirus 2019-nCoV Antigen Test(Colloidal Gold)	1T	盒/kit	0.039kg/盒 0.039kg / kit
	20T	盒/kit	0.884 kg/盒 0.884 kg / kit

抗原胶体金试剂盒出口包装箱

Novel Coronavirus 2019-nCoV Antigen Test(Colloidal Gold)

Export Packing Cartons

包装箱/盒 Packing Carton/ box	长 length cm	宽 Width cm	高 height cm	规格 **Specifications**	每箱装盒数量 Kit quantity per carton	单盒试剂净重 Net weight of single kit	整箱净重 Net weight of the whole carton	抛重 Throwing weight
纸箱 carton	70.5	40	39	1T	320 盒 320 kits	0.039 公斤 0.039kg	12.48 公斤 12.48 kg	18.5-19 公斤/kg
纸箱 carton	70.5	40	39	20T	16 盒 16 kits	0.884 公斤 0.884 kg	14.14 公斤 14.14 kg	18.5 - 19 公斤/kg

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Clinical Trial Summary Report

Research product name: Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Test start time: May 6th,2020

Test completion time: Aug.13th,2020

Model specifications: 40T/kit

Medical institutions undertaking clinical trials:

Fifth Medical Center of General Hospital of Chinese People's Liberation Army

The Sixth People's Hospital of Shenyang

Institute of Microbiology and Epidemiology, Academy of Military Medical Sciences

Peking Union Medical College Hospital, Chinese Academy of Medical Sciences

PLA Third Medical Center

Applicant: Beijing Hotgen Biotech Co., Ltd.

Reporting time: Aug.17th,2020

Beijing Hotgen Biotech Co., Ltd.

Summary of Research Report

Clinical trial sponsor	Beijing Hotgen Biotech Co., Ltd.
Clinical trial name	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
Clinical trial facility	Fifth Medical Center of General Hospital of Chinese People's Liberation Army,The Sixth People's Hospital of Shenyang,Institute of Microbiology and Epidemiology Academy of Military Medical Sciences,Peking Union Medical College Hospital Chinese Academy of Medical Sciences,PLA Third Medical Center
Purpose of clinical trials	Examine the clinical performance of the Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) for the detection of novel coronavirus 2019-nCoV antigen in human nasal swabs or throat swabs.
Clinical trial methods	In this clinical trial, the diagnostic criteria for the diagnosis of Coronavirus disease (COVID-19) infection and the results of the disease process (real-time fluorescent RT-PCR detection of novel coronavirus 2019-nCoV nucleic acid results, virus gene sequencing comparison) were selected as comparative methods for comparative research. Test results on clinical case samples. Statistics and calculation of the detection coincidence rate of the two. The differential samples should be fully analyzed in combination with the patient's epidemiological background, clinical symptoms, and disease outcomes to assess the Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) produced by Beijing Hotgen Biotech Co., Ltd. is used to qualitatively test the clinical performance of the novel coronavirus 2019-nCoV antigen in human nasal swabs or throat swabs.
Test kit name, specifications, batch number	Name: Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Specification: 40 Tests/Kit; Lot number: W2020040300
Sample size	The total number of nasal swabs samples was 207 cases of NDV positive samples and 410 cases of NDV negative samples; The total number of throat swabs samples was 201 cases of NDV positive samples and 402 cases of NDV negative samples; Negative nasal swabs samples included 10 cases of HBsAg positive, 7 cases of HCV positive, 2 cases of HIV positive, 6 cases of abnormal liver function, 7 cases of abnormal renal function, 3

<table>
<tr><td></td><td>cases of abnormal blood glucose, influenza A, influenza B, and mycoplasma pneumoniae, Fever, upper respiratory tract infection, viral hepatitis, cirrhosis, brucellosis, etc. Negative throat swabs samples included 9 cases of HBsAg positive, 6 cases of HCV positive, 2 cases of HIV positive, 5 cases of abnormal liver function, 6 cases of abnormal renal function, 3 cases of abnormal blood glucose, influenza A, influenza B, and mycoplasma pneumoniae, Fever, upper respiratory tract infection, viral hepatitis, cirrhosis, brucellosis, etc.</td></tr>
<tr><td>Judgment method</td><td>Visual observation</td></tr>
<tr><td>Evaluation method</td><td>(1) The total coincidence rate of the diagnosis results of the assessment system and the reference system is greater than 80%.
(2) The Kappa value of the consistency between the diagnostic results of the assessment system and the reference system is greater than 0.75.</td></tr>
<tr><td>Results and conclusions</td><td>1、The sensitivity , spesitivity , and accuracy of the diagnostic results of the assessment system and the reference system are:
Nasal swabs samples, 96.62%, 99.76%, and 98.70%
Throat swabs samples,96.02%,98.51%,97.69%
(1) human nasal swabs
<table>
<tr><td rowspan="2">Assessment system
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)</td><td colspan="3">Reference system (clinical diagnostic results)</td></tr>
<tr><td>Positive（+）</td><td>Negative（—）</td><td>Total</td></tr>
<tr><td>Positive（+）</td><td>200</td><td>1</td><td>201</td></tr>
<tr><td>Negative（—）</td><td>7</td><td>409</td><td>416</td></tr>
<tr><td>Total</td><td>207</td><td>410</td><td>617</td></tr>
</table>
Sensitivity：96.62%
Spesitivity：99.76%
Accuracy：98.70%
Confidence interval analysis with a total compliance rate of 95%:
<table>
<tr><td>Total compliance</td><td colspan="2">95% confidence interval</td></tr>
<tr><td>98.70%</td><td>97.46%</td><td>99.44%</td></tr>
</table></td></tr>
</table>

(2) human throat swabs

Assessment system Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Reference system (clinical diagnostic results)		
	Positive（+）	Negative(—)	Total
Positive（+）	199	14	213
Negative（—）	2	388	390
Total	201	402	603

Sensitivity：96.02%

Spesitivity：98.51%

Accuracy：97.68%

Confidence interval analysis with a total compliance rate of 95%:

Total compliance	95% confidence interval	
97.68%	96.14%	98.72%

2、The consistency coefficient Kappa result of the diagnostic results between the assessment system and the reference system is below:

Nasal swabs samples: Kappa（K）=0.9416;

Throat swabs samples:Kappa（K）=0.9476;

The assessment system can meet the current needs of clinical detection of the novel coronavirus 2019-nCoV antigen, and can be used to qualitatively detect the content of novel coronavirus 2019-nCoV antigen in human nasal swabs or throat swabs.

Verification unit: The Key laboratory of Biological Emergency and Clinical POCT (Beijing)

Aug.17th,2020

Note: The Key laboratory of Biological Emergency and Clinical POCT (Beijing) was jointly declared by Beijing Hotgen Biotech Co.,Ltd and institute of Microbiology of the Academy of Military Medical Sciences. It was announced on the website of the Beijing Municipal science & Technnology Commission on May 30, 2014.

Sensitivity verification of Novel Coronavirus 2019-nCoV

Antigen Test (Colloidal Gold)

Purpose

Use inactivated new coronavirus to evaluate the sensitivity of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Experimental Materials

1. 1 batch of colloidal gold test paper;
2. Inactivated virus: 10^5 pfu/mL.

Experimental steps

Sample: Mixing ratio of sample diluent

Concentration number	Virus content in sample (pfu/mL)	Sample: Mixing ratio of sample diluent
1	0	1：9
2	10^2	1：9
3	2.5×10^2	1：9
4	5×10^2	1：9
5	10^3	1：9
6	10^4	1：9

1. After mixing the sample and diluent, incubate at room temperature for 1 min.
2. Take 100μL of sample and observe the result after 15min reaction.

Test results

Concentration number	Virus content in sample (pfu/mL)	Sample: Mixing ratio of sample diluent	Result
1	0	1：9	-
2	10^2	1：9	±
3	2.5×10^2	1：9	+
4	5×10^2	1：9	+
5	10^3	1：9	++
6	10^4	1：9	+++

In conclusion

Colloidal gold experiment results: 10^2 pfu/mL has a shallow band, negative without background, the sensitivity is 2.5×10^2 pfu/mL.

The Key laboratory of Biological Emergency and Clinical POCT (Beijing)

Aug.17th,2020

空运货物运输条件识别报告书
Certificate for Safe Transport of Air Cargo

证 书 编 号：	BN2009720700750002
物 品 名 称：	新型冠状病毒（2019nCoV）抗原检测试剂盒（胶体金法）
Name of Goods：	NOVEL CORONAVIRUS 2019-nCoV ANTIGEN TEST (COLLOIDAL GOLD)
签 发 日 期：	2020-09-23
委 托 单 位：	北京热景生物技术股份有限公司
Applicant：	

北京信诺递捷运输咨询有限公司

SINO-Dangerous Goods Transportation Consultant Ltd.

电话：010-64589142　　网　址：www.chinasdg.cn
传真：010-64580462　　E-mail: public@chinasdg.cn
地址：北京市顺义区北京空港物流基地物流园八街九号林吉大厦B505室
邮编：101300

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00157950

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA22**		
	Bezeichnung / Name **Bezirksregierung Münster, Dezernat 24**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Münster**		Postleitzahl / Postal code **48143**
	Straße, Haus-Nr. / Street, house no. **Domplatz 36**		
	Telefon / Phone **+49-251-4110**		Telefax / Fax **+49-251-4112525**
	E-Mail / E-mail **mitteilungen-dimdi@brms.nrw.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **27.10.2020**		Registriernummer / Registration number **DE/CA22/419-1848-IVD**
	Typ der Anzeige / Notification type S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change £ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG £ Hersteller / Manufacturer S Bevollmächtigter / Authorised Representative £ Einführer / Importer £ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG £ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV £ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000012115**		
	Bezeichnung / Name **MedNet GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **Muenster**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **+49-251-32266-0**		Telefax / Fax **+49-251-32266-22**
	E-Mail / E-mail **ear-admin@medneteurope.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Beijing Hotgen Biotech Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Beijing**		Postleitzahl / Postal code **102600**
	Straße, Haus-Nr. / Street, house no. **9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District**		
	Telefon / Phone **0086-10-50973600**		Telefax / Fax
	E-Mail / E-mail		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Nicole Böhnisch**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **MÜNSTER**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **+49-251-32266-0**		Telefax / Fax **+49-251-32266-22**
	E-Mail / E-mail **info@medneteurope.com**		

Vertreter / Deputy (optional)

	Bezeichnung / Name **Kristin Zurlinden**		
	Telefon / Phone **+49 251 32266 0**		Telefax / Fax **+49 251 32266 22**
	E-Mail / E-mail **info@medneteurope.com**		
	£ Erstanzeige / Initial notification S Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device

	Klassifizierung / Classification £ Produkt der Liste A, Anhang II / Device of List A, Annex II £ Produkt der Liste B, Anhang II / Device of List B, Annex II £ Produkt zur Eigenanwendung / Device for self-testing S Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
	App (Software auf mobilen Endgeräten) £ ja / yes S nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG S "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device **CORA CHECK-19**
	Produktbezeichnung / Name of device **Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)**
	Angabe der benutzten Nomenklatur / Nomenclature used S EDMS-Klassifikation / EDMS Classification £ GMDN
	Nomenklaturcode / Nomenclature code **15-04-80-90-00**
	Nomenklaturbezeichnung / Nomenclature term **OTHER VIRAL ANTIGEN/ANTIBODY DETECTION**
	Kurzbeschreibung / Short description In Deutsch / In German **Dieser Kit dient zur qualitativen In-vitro-Bestimmung des neuartigen Coronavirus-Antigens in humanen Nasen- oder Rachenabstrichen, als Schnelluntersuchung bei Verdacht auf neuartiges Coronaviruskann auch als Bestätigungsmethode für den Nukleinsäure-Nachweis in entlassenen Fällen.** **Ein positives Testergebnis weist darauf hin, dass die Proben neuartiges Coronavirus-Antigen enthielten.** **Ein negatives Testergebnis schließt die Möglichkeit einer Infektion nicht aus.**
	In Englisch / In English **This kit is used for in-vitro qualitative determination of novel coronavirus antigen in human nasal swabs or throat swabs. It is used as rapid investigation for suspected cases of novel coronaviruscan also be used as a reconfirmation method for nucleic acid detection in discharged cases.** **A positive test result indicates that the samples contained novel coronavirus antigen. A negative test result does not rule out the possibility of infection.**

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	£ In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Münster**

Datum
Date **2020-09-10**

Name **Nicole Böhnisch**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Silvia Wenge**		Telefon / Phone **0251-4115936**

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 089675 0005 Rev. 00

Holder of Certificate: **Beijing Hotgen Biotech Co.,Ltd**
9th Building, No. 9 Tianfu Street, Biomedical Base
Daxing District
102600 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Beijing Hotgen Biotech Co.,Ltd
9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District,
102600 Beijing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production, Distribution and Service of Automated Immunoassay Analyzer, Up-converting Phosphor Immunoassay Analyzer, Up-converting Phosphor Technology Test Kits, Colloidal Gold Test Kits, Chemiluminescence Immunoassay Test Kits, Enzyme-Linked Immunoassay Test Kits.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ18712021

Valid from: 2018-11-14
Valid until: 2020-12-04

Date, 2018-11-14

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

对外贸易经营者备案登记表

备案登记表编号：01716790　　统一社会信用代码：91110115777090586H
进出口企业代码：

经营者中文名称	北京热景生物技术股份有限公司		
经营者英文名称	Beijing Hotgen Biotech Co.,Ltd.		
组织机构代码		经营者类型（由备案登记机关填写）	股份有限公司
住　所	北京市大兴区中关村科技园区大兴生物医药产业基地天富街9号9幢		
经营场所（中文）	北京市大兴区中关村科技园区大兴生物医药产业基地天富街9号9幢		
经营场所（英文）	9th Building，No.9 Tianfu St，Biomedical Base,Daxing District,Beijing, China		
联系电话		联系传真	010-56528861
邮政编码	102600	电子邮箱	li.han@hotgen.com.cn
工商登记注册日期	2005-6-23	工商登记注册号	

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	林长青	有效证件号	352202197609261014
注册资金	肆仟伍佰万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人 个体工商负责人姓名		有效证件号	
企业资产/个人财产			（折美元）

备注	地址、变更，原证号01224263 名称、经营者类型、注册资金变更， 原证号01224414

填表前请认真阅读背面的条款　　此由企业法定代表人或个体工商负责人签字

医疗器械生产许可证

许可证编号：京食药监械生产许20070010号

企业名称：北京热景生物技术股份有限公司

生产地址：北京市大兴区中关村科技园区大兴生物医药产业基地天富街9号9幢

法定代表人：林长青

生产范围：

2002版分类目录：II类：II-6840-3免疫分析系统，II-6840体外诊断试剂 III类：III-6840-3免疫分析系统，III-6840体外诊断试剂***

2017版分类目录：II类：II-22-04免疫分析设备 III类：III-22-15检验及其他辅助设备***

企业负责人：林长青

住　　所：北京市大兴区中关村科技园区大兴生物医药产业基地天富街9号9幢

发证部门：北京市药品监督管理局

有效期限：至　2024　年　08　月　15　日

发证日期：2020　年　01　月　10　日

国家药品监督管理局制

印刷流水号NO: 0004196

统一社会信用代码

91110115777090586H

营业执照

（副　本）(2-1)

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息

名　　称　北京热景生物技术股份有限公司

类　　型　股份有限公司(上市、自然人投资或控股)

法定代表人　林长青

经营范围　技术开发、技术转让、技术服务、技术咨询；货物进出口；技术进出口；代理进出口；租赁、维修医疗器械；销售医疗器械（Ⅱ类）；软件开发；健康咨询（须经审批的诊疗活动除外）；生产第二类、第三类医疗器械；销售食品；销售第三类医疗器械。（企业依法自主选择经营项目，开展经营活动；生产第二类、第三类医疗器械、销售食品、销售第三类医疗器械以及依法须经批准的项目，经相关部门批准后依批准的内容开展经营活动；不得从事本市产业政策禁止和限制类项目的经营活动。）

注册资本　6219.6341万元

成立日期　2005年06月23日

营业期限　2005年06月23日至 长期

住　　所　北京市大兴区中关村科技园区大兴生物医药产业基地天富街9号9幢

登记机关　北京市大兴区市场监督管理局

2019 年 11 月 25 日