Hotgen

Stock Code： 688068.SH

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

Beijing Hotgen Biotech Co., Ltd.

Explanation of The Export License

To whom it may concern

According to the No.12 Government Notice published by MOC, GAC and NMPA, CCCMHPIE announced the list of companies which were permitted to export novel coronavirus diagnostic products, Hotgen is in the list as aforesaid.

中国医药保健品进出口商会
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English 请输入关键词进行搜索

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10	北京热景生物技术股份有限公司 Beijing Hotgen biotech Co., Ltd.	91110115777090586H	欧盟CE

Beijing Hotgen biotech Co., Ltd.

2020-11-23

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

Email: sales@hotgen.com.cn Website: www.hotgen.com.cn

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Hotgen

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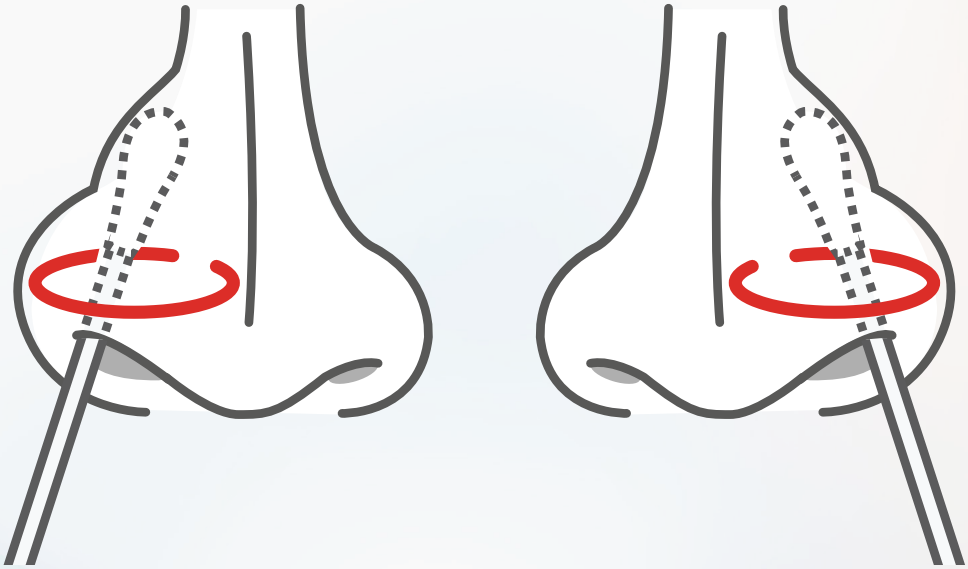


Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

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)

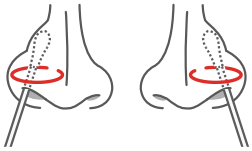
Specimen Requirements

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.

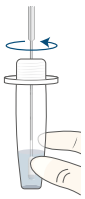
Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 4 times for a total time of 15 seconds.

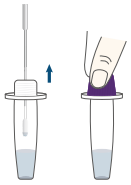
Repeat the same process with the same swab in the other nostril.



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.



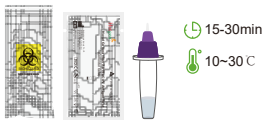


The swab head is pressed, then take out the swab and tighten the sampling tube.

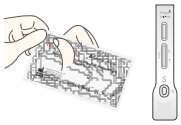
③ Sample preservation

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.

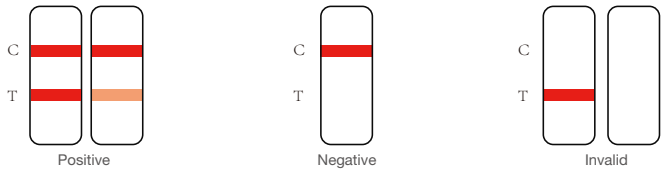
③

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!

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:

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

CE

Signature: Lin Changqing

Name: Lin Changqing

Title: General manager

Place: Beijing,China.

Date of Issue: Aug 27, 2020

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

[redacted]

Anzeige / Notification

Registrierdatum bei der zuständigen Behörde Registration date at competent authority **25.01.2021**	Registriernummer / Registration number **DE/CA22/419-1848.1-IVD**

Typ der Anzeige / Notification type

- 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
DE/CA22/419-1848-IVD

Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG

- Hersteller / Manufacturer
- 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

[redacted]

Hersteller / Manufacturer

Bezeichnung / Name
Beijing Hotgen Biotech Co., Ltd.

Staat / State
CN

Ort / City	Postleitzahl / Postal code
Beijing	**102600**

Straße, Haus-Nr. / Street, house no.
9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District

Telefon / Phone	Telefax / Fax
0086-10-50973600	

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

Ort / City
MÜNSTER

[redacted]

Vertreter / Deputy (optional)

Bezeichnung / Name
Kristin Zurlinden

[redacted]

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 Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
	App (Software auf mobilen Endgeräten) ja / yes nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device **Hotgen Biotech, CORA CHECK-19**
	Produktbezeichnung / Name of device **Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)**
	Angabe der benutzten Nomenklatur / Nomenclature used 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 **Modelle A+B:** **Dieser Kit wird für die qualitative In-vitro-Bestimmung von neuem Coronavirus-Antigen in menschlichen Nasen- oder Rachenabstrichen verwendet. Er dient zur schnellen Untersuchung von Verdachtsfällen auf neuartige Coronaviren und kann auch als Bestätigungsmethode für den Nukleinsäurenachweis in entladenen Fällen verwendet werden.** **Modelle C+D (Neuartiges Coronavirus 2019-nCoV-Antigentest (kolloidales Gold) - Speichel):** **Dieser Kit dient zur qualitativen in vitro-Bestimmung des neuen Coronavirus-Antigens im menschlichen Speichel. Er dient zur Schnelluntersuchung bei Verdacht auf neuartige Coronaviren und kann auch als Bestätigungsmethode für den Nukleinsäurenachweis in entladenen Fällen verwendet werden.**
	In Englisch / In English **Models A+B:** **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.** **Models C+D (Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) - Saliva):** **This kit is used for in vitro qualitative determination of novel coronavirus antigen in human saliva. 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.**

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 **2021-01-15**

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**

Hotgen

CE

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Instructions for Use

FREQUENTLY ASKED QUESTIONS

- When can I test myself?

You can always test yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated according to the regulations of the responsible authorities.

- What should I pay attention to in order to obtain the most exact test result possible?

Always follow the instructions for use exactly. Perform the test immediately after collecting the sample. Dispense the drops from the test tube only into the designated well of the test cassette. Dispense four drops from the sample tube. Too many or too few drops can lead to an incorrect or invalid test result.

- The test strip is very discolored. What is the reason or what am I doing wrong?

The reason for a clearly visible discoloration of the test strip is that too large a quantity of drops has been dispensed from the sample tube into the test cassette well. The indicator strip can only hold a limited amount of liquid. If the control line does not appear or the test strip is very discolored, please repeat the test with a new test kit according to the instructions for use.

- What should I do if I took the test but didn't see a control line?

In this case, the test result is to be considered invalid. Please repeat the test with a new test kit according to the instructions for use.

- I am unsure of the interpretation of the results. What should I do?

If you cannot clearly determine the result of the test, contact the nearest medical facility applying the regulations of your local authority.

- My result is positive. What should I do?

If a horizontal colored line is visible in the control area (C) as well as in the test area (T), your result is positive and you should immediately contact the medical facility in accordance with the requirements of your local authorities. Your test result may be checked and the next steps will be explained to you.

- My result is negative. What should I do?

If only a horizontal colored line is visible in the control area (C), this may mean that you are negative or that the viral load is too low to be recognized by the test. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest medical facility applying the regulations of your local authority. In addition, you can repeat the test with a new test kit.

- Can this test cassette be reused or used by multiple people?

This test cassette is for one-time use and cannot be reused or used by multiple people.

MODEL NUMBER

Model A

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 SARS-CoV-2 antigens in human anterior nasal swab samples. It can be used for rapid investigation of suspected COVID-19 cases, and can also be used as a reconfirmation method for nucleic acid detection in discharged cases.

A positive test result indicates that the sample contains SARS-CoV-2 antigen. A negative test result does not rule out the possibility of infection.

This kit is for home use by laymen in a non-laboratory setting (such as person's home or certain non-traditional sites such as offices, sporting events, airports, schools etc.). 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.

COMPONENTS

1. SARS-CoV-2 Antigen Test Cassette
2. Sample extraction buffer
3. Disposable virus sampling swab
4. Biohazard specimen bag

Note: Components of different batches cannot be mixed.

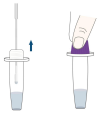
SPECIMEN REQUIREMENTS

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 15 seconds.



- 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 chromatographic abnormalities, add an extra of 1~2 drops of the treated sample accordingly). Incubate at 10~30℃ for 15 minutes.
4. Observe the results after Incubating at 10~30℃ for 15 minutes. The result obtained after 30 minutes is invalid.

DISPOSAL THE SAMPLE AND CLEAN-UP

- Place the test cassette, sample extraction buffer and disposable virus sampling swab in the biohazard specimen bag and seal the bag.

- Throw away the remaining sample kit items.

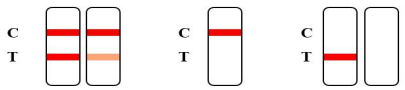
- Re-apply hand sanitizer.

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), indicating the test result of SARS-CoV-2 antigens in the sample is 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 result of the SARS-CoV-2 antigens in the sample is negative or the concentration is 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), indicating that the test is invalid, and the sample should be recollect and retested.



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

PRINCIPLE OF THE ASSAY

This kit is based on the colloidal gold immunochromatographic technology, and uses the double antibody sandwich method to detect N protein of SARS-CoV-2 antigen in human anterior nasal swab samples. The detection line (T line) of the SARS-CoV-2 antigen test cassette was coated with SARS-CoV-2 antibody, and the quality control line (C line) was coated with sheep anti-mouse antibody. During the test, the sample is dropped into the test cassette and the liquid is chromatographed upward under the capillary effect. The SARS-CoV-2 antigen in the sample first binds to the colloidal gold-labelled SARS-CoV-2 antibody to form a solid phase SARS-CoV-2 antibody-SARS-CoV-2 antigen-labelled SARS-CoV-2 antibody-colloidal gold complex at the T line position, and form a solid phase sheep anti-mouse-labelled SARS-CoV-2 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 SARS-CoV-2 antigen in human anterior nasal swab samples.

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℃, 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

IVD

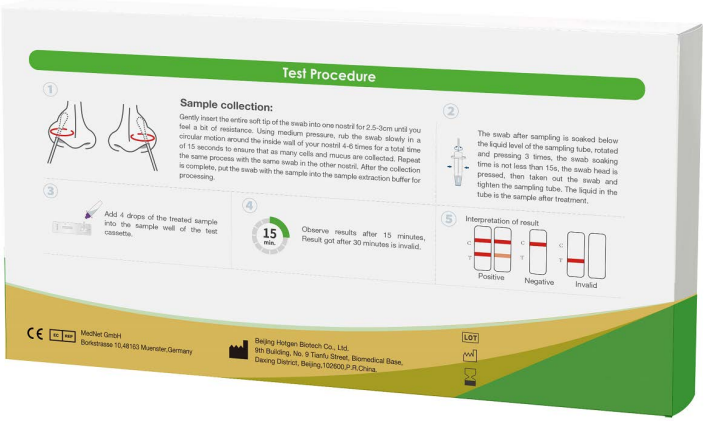
APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION

Approved on February, 2021;

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

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Product Photos



抗原胶体金检测试剂包装信息

Novel Coronavirus 2019-nCoV Antigen Test(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	0.0359 kg/盒 0.0359 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	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	71	40	39	320盒 320kits	0.0359 公斤 0.0359 kg	11.488公斤 11.488 kg	18.5-19公斤 18.5-19 kg

Novel Coronavirus 2019-nCoV Antigen Test

(Colloidal Gold)

Clinical Study Report

Subject Product: Novel Coronavirus 2019-nCoV Antigen Test

(Colloidal Gold)

Test start time: Oct.10 th, 2020

Test completion time: Feb. 03th, 2021

Model specifications: 40T/kit

Submitted by: Beijing Hotgen Biotech Co., Ltd.

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	The Key laboratory of Biological Emergency and Clinical POCT (Beijing)
Purpose of clinical trials	The purpose of this study was to investigate the self-test performance of "Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)" produced by Beijing Hotgen Biotech Co., Ltd. to detect novel coronavirus (2019-nCoV) antigen in human anterior nasal swab specimens.
Clinical trial methods	The subject product of this study is "Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)" (*hereinafter referred to as "Antigen Test"*) produced by Beijing Hotgen Biotech Co., Ltd. The product selected for the comparison is RT-PCR Kit. Results of the Antigen Test and RT-PCR Test are compared to evaluate the consistency between the Antigen Test and RT-PCR Test. Cases with different test results were comprehensively analyzed by combining the patients' epidemiological background, clinical symptoms, disease outcome, and other information. In this way, the performance of the Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) (produced by Beijing Hotgen Biotech Co., Ltd) to detect the novel coronavirus (2019-nCoV) antigen in human anterior nasal swab specimens was evaluated. The specimens collection and testing for antigen test were conducted by individuals in non-healthcare settings while the collection and testing of the specimens for RT-PCT were accomplished by the investigators. The anterior nasal swab specimens used for antigen test were prospectively collected. Patients were sequentially and randomly enrolled .All collected specimens can be traced back to the corresponding clinical information, including case number, age, gender, type of specimens, collection time, confirmation or exclusion of the novel coronavirus infection, and the RT-PCR Test results for disease diagnosis.
Test kit name, specifications	Name: Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Specification: 40 Tests/Kit;
Sample size	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.
Judgment method	Visual observation
Evaluation method	(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.
Results and conclusions	1、The sensitivity , spesitivity , and accuracy of the diagnostic results of the assessment system and the reference system are: Human anterior nares swab specimens, 96.30%, 99.13%, and 97.76%

		Nucleic Acid Test results		Total
		Positive (+)	Negative (-)	
Antigen Test	Positive (+)	104	1	105
	Negative (-)	4	114	118
Total		108	115	223

Sensitivity: 96.30% (90.79%～98.98%)
Specificity: 99.13% (95.25%～99.98%)
Accuracy: 97.76% (94.85%～99.27%)

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

Human anterior nares swab specimens: Kappa（K）=0.9551;

In summary, individuals self-test in non-healthcare settings by using the Antigen Test kit , the Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) produced by Beijing Hotgen Biotech Co., Ltd. to detect human anterior nasal swab specimens, the results showed excellent agreement with the RT-PCR Test results. The comparison test results of human anterior nasal swab specimens are highly consistent. Therefore, the Antigen Test kit has a good self-test performance.

Verification unit:

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

生物应急与临床POCT 北京市重点实验室

Feb.03th , 2021

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
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DAkkS
Deutsche
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D-ZM-11321-01-00

Product Service

Certificate

No. Q5 089675 0005 Rev. 01

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:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and 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

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Report No.: BJ20071201

Valid from: 2020-12-05
Valid until: 2023-12-04

Date, 2020-09-01

Christoph Dicks
Head of Certification/Notified Body

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

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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	010-56528860	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，并由企业法定代表人或个体工商负责人签字

备案登记机关 专用章（北京大兴）

2016 年 07 月 29 日

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)

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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

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制