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.

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

目录

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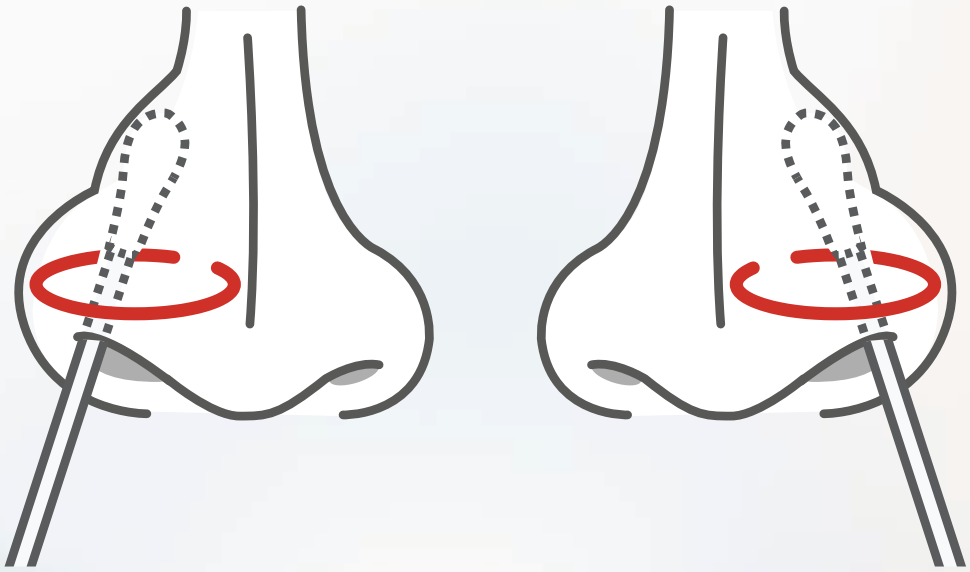
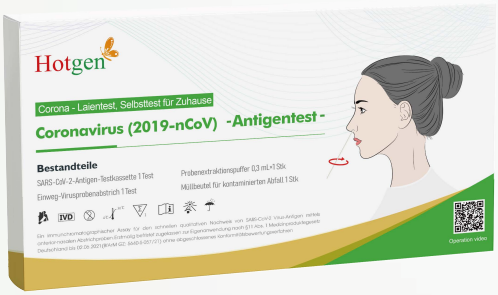
Hotgen

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 : Human Anterior Nares Swab
- Detect the presence of viral proteins
- Identify acute or early infection

Clinical Performance

(Disease Course 5-7 Days)

Sensitivity: **95.37%**; **Specificity**: **99.13%** ; **Accuracy: 97.31%.**

CE

Novel Coronavirus 2019-nCoV Antigen Test(Colloidal Gold)

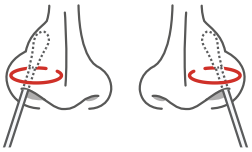
Specimen Requirements

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.

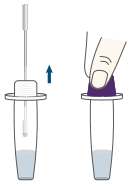
Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 4 times for a total time of 15 seconds.

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 ☒at surface.

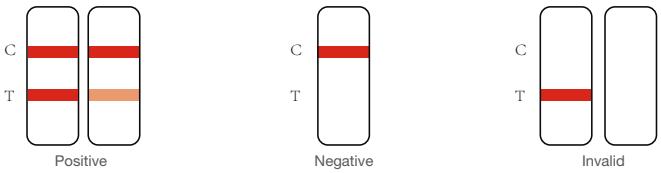
③ 

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(+)	103	1	105
Negative(-)	5	114	118
Total	108	115	223

Sensitivity: 95.37%; Specificity: 99.13 %; Accuracy: 97.31%.

Product information

Product name	Test samples	Speci☒cations	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:

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

CE

Signature: Lin Changqing

Name: Lin Changqing

Title: General manager

Place: Beijing,China.

Date of Issue: Aug 27, 2020

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00161406

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 **26.02.2021**		Registriernummer / Registration number **DE/CA22/419-1848.2-IVD**
	Rechtsgrundlage / Legacy basis ☒ Medizinprodukte (98/79/EG) / German Medical Device Act (98/79/EG) ☐ Verordnung (EU) 2017/746 (IVDR) / Regulation (EU) 2017/746 (IVDR)		
	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/CA22/419-1848.1-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**		
	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 ☒ 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 ☒ 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.** **Modell E (SARS-CoV-2-Antigentest (kolloidales Gold):** **Dieser Kit dient der qualitativen in vitro-Bestimmung von SARS-CoV-2-Antigen in humanen anterioren Nasenabstrichproben. Er dient zur Schnelluntersuchung bei Verdachtsfällen auf ein neuartiges Coronavirus, kann aber 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.** **Model E (SARS-CoV-2 Antigen Test (Colloidal Gold):** **This kit is used for in vitro qualitative determination of SARS-CoV-2 antigen in human anterior nasal swab samples. 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 **2021-02-18**

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**

Medicines & Healthcare products
Regulatory Agency

MHRA

Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000
gov.uk/mhra

Medimap Ltd
2 The Drift
Suffolk
Thurston
IP31 3RT
United Kingdom

27 February 2021

Dear **Tracey Oakey**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **26 February 2021** has been reviewed:

Application reference: **2021022601194301**

Manufacturer organisation: **Beijing Hotgen Biotech Co Ltd**
Address:
9th Building, No 9 Tianfu Street, Biomedical Base
Daxing District
Beijing
102600
China

Manufacturer registration status: **Registered**

Device(s):

GMDN term	Status	MHRA comment
64787 - SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
64956 - SARS-CoV-2 immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, immunochromatographic test (ICT), rapid	Registered	
65315 - SARS-CoV-2/Influenza A/B antigen IVD, kit, immunochromatographic test (ICT), rapid	Registered	
65147 - SARS-CoV-2 antigen IVD, kit, chemiluminescent immunoassay	Registered	
65300 - SARS-CoV-2 neutralizing antibody IVD, kit, chemiluminescent immunoassay	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration Database (PARD). This applies to non-in vitro diagnostic devices only.

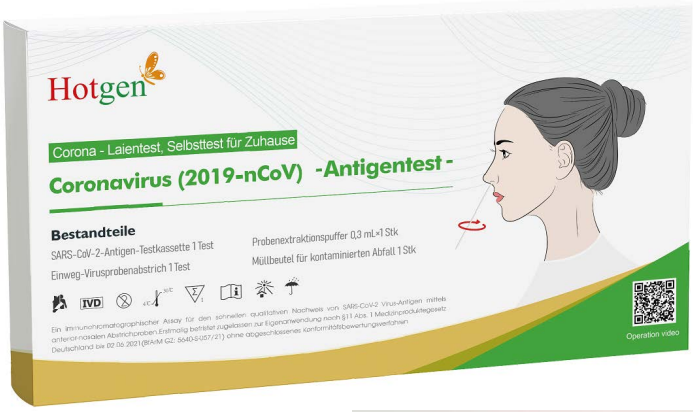
The account number for your company/organisation is **0000012377.**

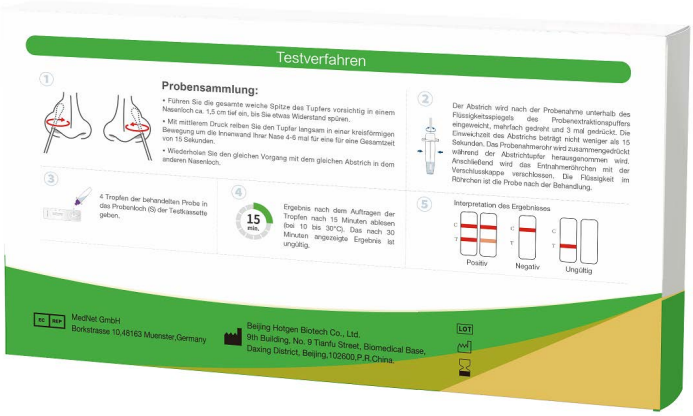
Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
MHRA

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Product Photos





前鼻腔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	0.033 kg/盒 0.033 kg / kit

前鼻腔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	0.033 公斤 0.033 kg	10.56公斤 10.56 kg	18.5-19公 18.5-19 kg

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

中国认可
检验
INSPECTION
CNAS IB0126

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

DAkkS
Deutsche Akkreditierungsstelle
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

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 089675 0005 Rev. 01

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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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（盖章）

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)

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

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