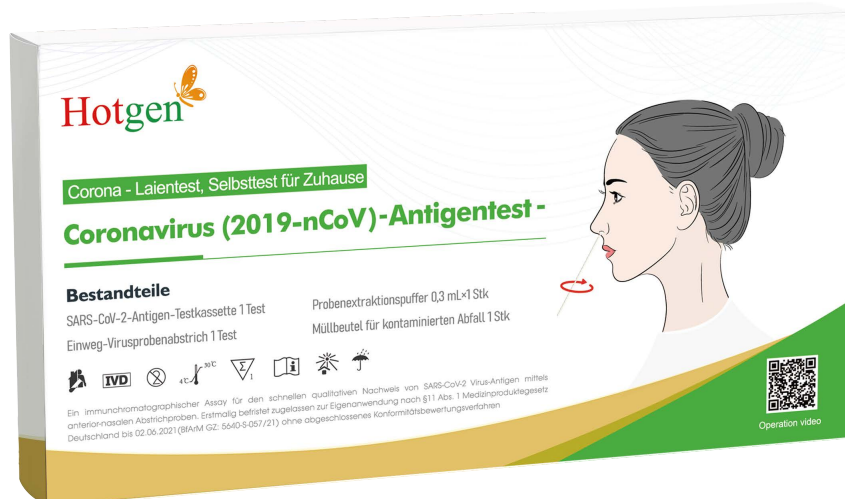




Stock Code: 688068.SH

Coronavirus (2019-nCoV)-Antigentest - 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.



The screenshot shows the website of the China Council for the Promotion of International Trade (CCPIT) China Pharmaceutical and Health Products Import and Export Association (CCCMHPIE). The page displays a table with the following information:

序号	关于商号	注册中心	行业服务	权威发布	商协会刊	企业风采	会员之家	加入商协
10	北京热景生物技术股份有限公司 Beijing Hotgen biotech Co., Ltd.							

Beijing Hotgen biotech Co., Ltd.



目录

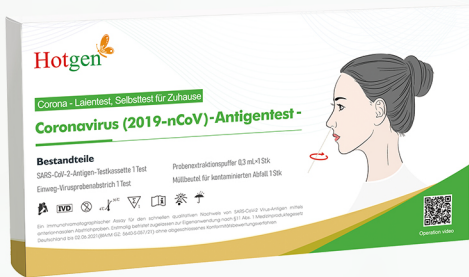
(Contents)

1、产品彩页 (Product Brochure)	1-2
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Corona -Laientest, Selbsttest für Zuhause

Coronavirus (2019-nCoV)-Antigentest -



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%.



Specimen Requirements and Test Procedure

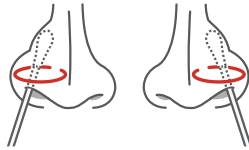
Specimen Requirements

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.

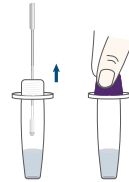
Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 4 times for a total time of 15 seconds.

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

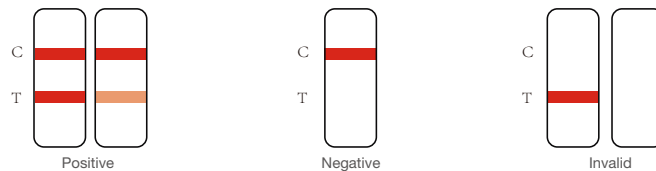
1 Place the test cassette, sample extraction buffer at room temperature for 15-30 minutes, and equilibrate to room temperature (10-30 C).

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, extra add 1-2 drops of the treated sample accordingly.) Incubate at 10-30 C for 15 minutes.

4 Observe the results after incubate at 10-30 C 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	Specifications	Storage conditions
Coronavirus (2019-nCoV)-Antigen test -	Human Anterior Nares Swab	1T/kit, 5T/kit, 20T/kit, 40T/kit	4-30 C

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.

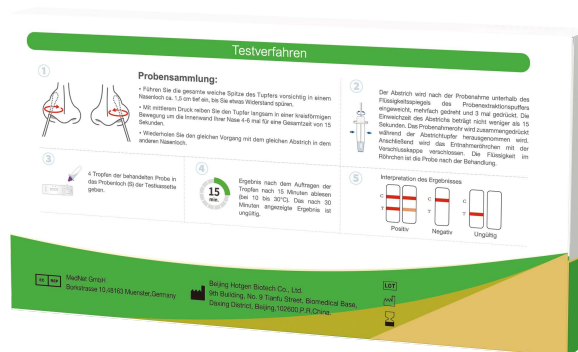
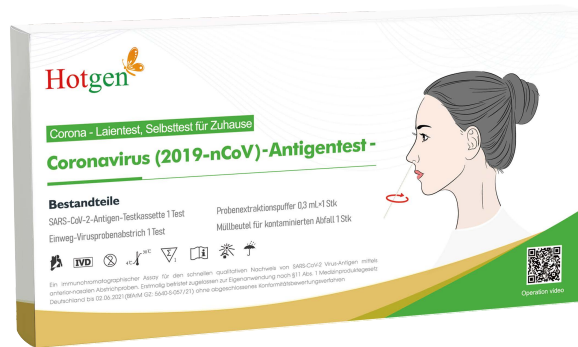
After several years of Research& development, Hotgen Biotech has developed an in vitro diagnostic reagent bioactive raw material development platform, a sugar chain abnormal protein detection (sugar capture) R&D technology platform, a Magnetic particles chemiluminescence R&D technology platform, a Up-converting 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!

Coronavirus (2019-nCoV)-Antigentest - Product Photos



前鼻腔抗原胶体金检测试剂包装信息
Coronavirus (2019-nCoV)-Antigentest - 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
Coronavirus (2019-nCoV)-Antigentest -	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 Coronavirus (2019-nCoV)-Antigentest - 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公斤 18.5-19 kg

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/个体工商户负责人姓名		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户负责人签字



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***

企业负责人：林长青

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***

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

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