



Coronavirus (2019-nCoV)-Antigentest - Summary Data

The image shows the front of a product box for the Hotgen Coronavirus (2019-nCoV)-Antigentest. The box is white with a green and yellow gradient at the bottom. It features the Hotgen logo, a butterfly icon, and a circular illustration of a woman using the test. The text is in multiple languages: English, German, French, and Spanish. The English text includes 'For self-testing use', 'Coronavirus (2019-nCoV)-Antigentest', and a list of components: SARS-CoV-2 antigen test cassette (1 test), Sample and reaction buffer (0.3 mL x 1 pcs), Disposable Swabs (1 test), and Buffer and specimen bag (1 pcs). The German text includes 'Für den Selbsttest', 'Coronavirus (2019-nCoV)-Antigentest', and a list of components: SARS-CoV-2 Antigen-Testkassette (1 Test), Reagenzien mit Extraktionslösung (1 SK), Steriler Einwegswab (1 Test), and Materialbeutel für Salivensprobe (1 SK). The French text includes 'Pour une utilisation d'auto-test', 'Coronavirus (2019-nCoV)-Antigentest', and a list of components: Cassette de prélèvement antigène SARS-CoV-2 (1 gravure), Tampon de extraction de muqueuse (1 pcs), Bâtonnet stérile monovue (1 test), and Sachets pour fluides et récipient biologique (1 pcs). The Spanish text includes 'Para uso de autodiagnóstico', 'Coronavirus (2019-nCoV)- Prueba de Antígeno', and a list of componentes: Cassete de prueba de antígeno SARS-CoV-2 (1 gravata), Tampon de extracción de mucosa (1 pcs), Hisopo estéril desechable (1 prueba), and Bolsa para muestras de riesgo biológico (1 pcs). The box also features a barcode, a QR code for an operation video, and various regulatory symbols including IVD, CE, and REF HCGG134S0101.

Beijing Hotgen Biotech Co., Ltd.

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Company Profile

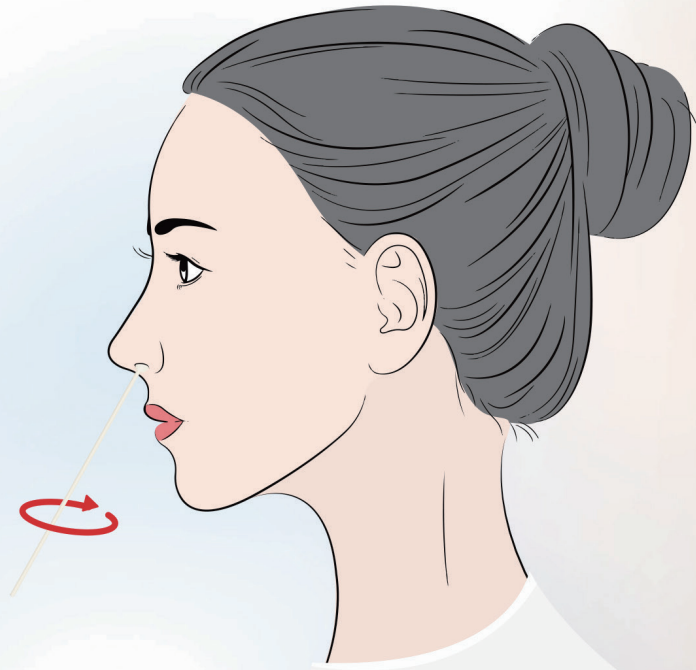
Beijing Hotgen Biotech Co., Ltd. (abbreviated as Hotgen Biotech, stock code: 688068) was established in June 2005, which is a high-tech enterprise focusing on the research& development, manufacture and sales of medical and public safety inspection products of in vitro diagnostics (IVD) in the field of 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 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 ●

Specimen Requirements and Test Procedure

Specimen Requirements

1

Please wash and dry your hands thoroughly before the test.



2

Read the Instructions for Use carefully.



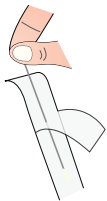
3

Please scan the QR code to watch the operation video.



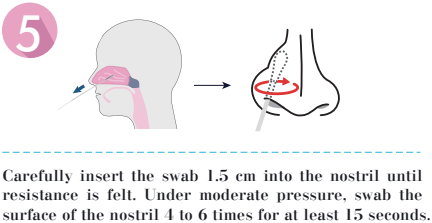
4

Take the swab out of the package and do not touch the sampling end.



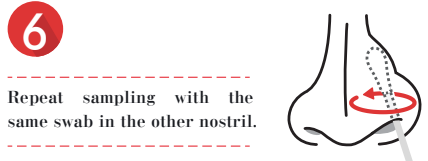
5

Carefully insert the swab 1.5 cm into the nostril until resistance is felt. Under moderate pressure, swab the surface of the nostril 4 to 6 times for at least 15 seconds.




6

Repeat sampling with the same swab in the other nostril.



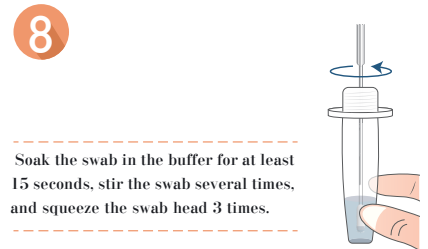
7

Open the larger end of the sampling tube, and insert the swab after collecting the sample into the sampling tube.




8

Soak the swab in the buffer for at least 15 seconds, stir the swab several times, and squeeze the swab head 3 times.



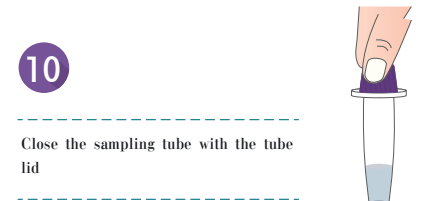
9

When remove the swab, squeeze the sides of the sampling tube.



10

Close the sampling tube with the tube lid



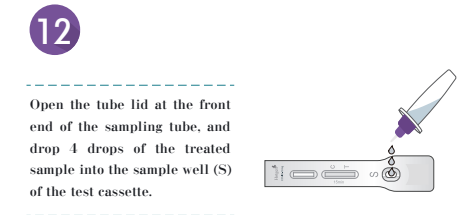
11

Open the foil pouch and place the test cassette on a flat surface.



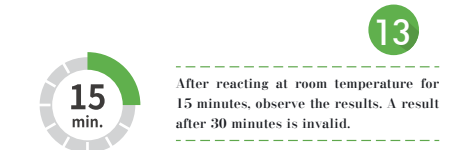
12

Open the tube lid at the front end of the sampling tube, and drop 4 drops of the treated sample into the sample well (S) of the test cassette.



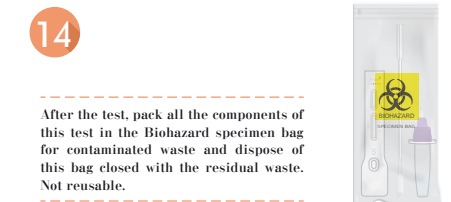
13

After reacting at room temperature for 15 minutes, observe the results. A result after 30 minutes is invalid.



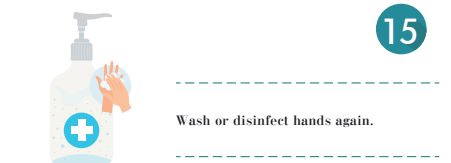
14

After the test, pack all the components of this test in the Biohazard specimen bag for contaminated waste and dispose of this bag closed with the residual waste. Not reusable.

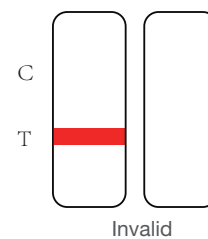
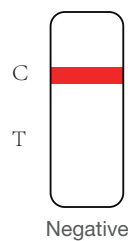
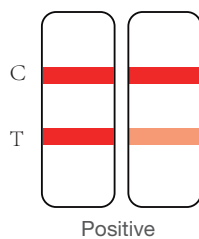


15

Wash or disinfect hands again.



Interpretation of result



Product information

Product name	Test samples	Specification	Storage conditions
Coronavirus (2019-nCoV)-Antigentest-	Human Anterior Nares Swab	1T/kit	4-30 C

Coronavirus (2019-nCoV)-Antigentest - Product Photos

Hotgen

For self-testing use

Coronavirus (2019-nCoV)-Antigentest-

Coronavirus (2019-nCoV)-Antigentest- Pour une utilisation d'auto-test
 Coronavirus (2019-nCoV)-Antigentest- Für den Selbsttest
 Coronavirus (2019-nCoV)- Test antigenico rapido- Per uso autodiagnostico
 Coronavirus (2019-nCoV)- Prueba de Antígeno- Para uso de autodiagnóstico

Components
 SARS-CoV-2 antigen test cassette 1 test
 Sample extraction buffer 0.3 mL x 1 pcs
 Disposable Sterile Swab 1 piece
 Refractor (specimen bag) 1 pcs
 Instructions for use 1 pcs

Composantes
 Cassette de test d'antigène SARS-CoV-2 1 test
 Tempois d'extraction d'échantillon 0.3 mL x 1 PCS
 Écouvillon stérile jetable 1 pièce
 Sac d'isolation (emballage) 1 PCS
 Mode d'emploi 1 PCS

Bestandteile
 SARS-CoV-2 Antigen Testkassette 1 Test
 Röhren mit Extraktionslösung 0.3k
 Steriler Einwegspatel 1 Test
 Müllbeutel für Geländeartikel 1Stk
 Gebrauchsanweisung 1Stk

Componenti
 Cass per test antigenico SARS-CoV-2 1 test
 Provetta di estrazione con buffer 1 pcs
 Tampone sterile monouso 1 test
 Sacchetto per rifiuti a rischio biologico 1 pcs
 Istruzioni per l'uso 1 pcs

Componentes
 Cassete de pruebas de antígeno SARS-CoV-2 1 prueba
 Tampon de extracción de muestras 1 pcs
 Hisopo estéril desechable 1 prueba
 Bolsa para muestras de riesgo biológico 1 pcs
 Instrucciones de uso 1 pcs

IVDI, CE 0123, REF: HGCG134SD101, 6 97 0297 534073, Operation video

Test Procedure

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 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.

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

4 15 min. Observe results after 15 minutes. Result got after 30 minutes is invalid.

5 Interpretation of result

Positive: C (red line), T (red line)
 Negative: C (red line), T (no red line)
 Invalid: C (no red line), T (red line)

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

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	袋/kit	0.031 kg/袋 0.031 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	每箱装袋 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	73	39	26	400袋 400T	0.031 公斤 0.031 kg	13.5公斤 13.5kg	12.3公斤 12.3kg

For reference only, shipping cost according to the actual weight of the airline department



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
(Devices for self-testing)

No. V9 089675 0006 Rev. 00

Manufacturer:

Beijing Hotgen Biotech Co.,Ltd

9th Building, No. 9 Tianfu Street, Biomedical Base

Daxing District

102600 Beijing

PEOPLE'S REPUBLIC OF CHINA

Product:

In Vitro diagnostic devices for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex II (6). The design of the devices conforms to the requirements of this Directive. 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:V9_089675_0006_Rev_00

Report No.:

BJ21071201

Valid from:

2021-08-04

Valid until:

2024-05-26

Date,

2021-08-04

Christoph Dicks

Head of Certification/Notified Body



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-245.10.07



Product Service

EC Certificate

EC Design-Examination Certificate
 Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex III (6)
 (Devices for self-testing)

No. V9 089675 0006 Rev. 00

Model(s): **Coronavirus (2019-nCoV)-Antigentest-**

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

Model Name:	REF number:
Coronavirus (2019-nCoV)-Antigentest-	HGCG134S0101
Coronavirus (2019-nCoV)-Antigentest-	HGCG134S0105
Coronavirus (2019-nCoV)-Antigentest-	HGCG134S0120
Coronavirus (2019-nCoV)-Antigentest-	HGCG134S0140

仅供外贸备案使用

Declaration of Conformity

Manufacturer: Beijing Hotgen Biotech Co.,Ltd.
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: Coronavirus (2019-nCoV)-Antigentest -

Model Number: HGCG134S0101 (1T/Kit) HGCG134S0105 (5T/Kit)
HGCG134S0120 (20T/Kit) HGCG134S0140 (40T/Kit)

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany

Classification : Self-testing

Conformity Assessment Route: Annex III.6 of the directive 98/79/EC



We, herewith declare on our solo responsibility that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Directives 98/79/EC and Standards. All supporting documentations are retained under the premises of the manufacturer.

We, Beijing Hotgen Biotech Co., Ltd., is exclusively responsibility for the DOC.

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 18113-4:2011; EN 13612:2002; EN ISO 17511:2003; EN ISO 23640:2015; EN 13641:2002; EN 62366:2008; EN 13532:2002

(EC) Certificate(s) No. V9 089675 0006 Rev. 00

Start of CE-Marking 2021-08-05

Signature:

Name: Lin changqing

Title: General manager

Place: Beijing





Elenco dei dispositivi medici

Criteri di ricerca:

Denominazione fabbricante:

Codice fiscale fabbricante:

Partita IVA / VAT number fabbricante:

Codice nazione fabbricante:

Denominazione mandatario:

Codice fiscale mandatario:

Partita IVA / VAT number mandatario:

Codice nazione mandatario:

Tipologia dispositivo:

Identificativo di registrazione attribuito dal sistema BD/RDM:

Codice attribuito dal fabbricante: **HGCG13450101**

Nome commerciale e modello:

Classificazione CND:

Descrizione CND:

Normativa:

Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:07/12/2021

DISPOSITIVO MEDICO/ASSEMBLATO								FABBRICANTE/ASSEMBLATORE					
IDENTIFICATIVO				NOME				DATA FINE		PARTITA			
TIPOLOGIA	DI	ISCRITTO AL	CODICE ATTRIBUITO DAL	COMMERCIALE	CND	NORMATIVA	CLASSE CE	DATA PRIMA	IMMISSIONE	RUOLO	DENOMINAZIONE	CODICE	PARTITA
DISPOSITIVO	REGISTRAZIONE	REPERTORIO	FABBRICANTE/ASSEMBLATORE	E MODELLO				PUBBLICAZIONE	IN	AZIENDA		FISCALE	IVA/VAT
	BD/RDM								COMMERCIO				NUMBER
Dispositivo	2150026	N	HGCG13450101	HOTGEN - TEST ANTIGENE COVID-19 - I TEST	W0105040619 CORONAVIRUS	D.L.vo 332/2000	ST - Test autodiagnostics (non inclusi nell'ail. II)	03/09/2021		FABBRICANTE	BEIJING HOTGEN BIOTECH CO. TTD		
										MANDATARIO	MEDNET GMBH		999999999

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