

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



Medicines & Healthcare products
Regulatory Agency



Medicines & Healthcare products
Regulatory Agency

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21 September 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 **25 August 2021** has been reviewed:

Application reference: **2021082501213362**

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	Comment
65454 - SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), self-testing	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 (PARDB).

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

Yours sincerely,



Ngozi Onyeukwu
Device registrations service
Devices division
MHRA



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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 III (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
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



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:



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?c=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

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.



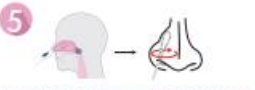
4

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.



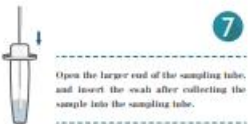
6

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.



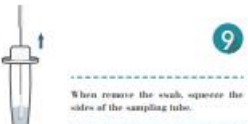
8

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.



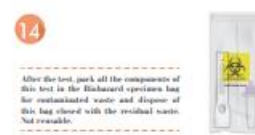
13

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.

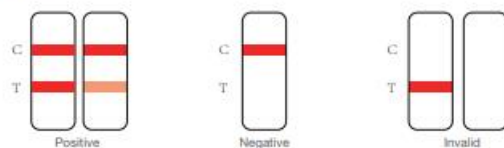


15

Wash or disinfect hands again.



Interpretation of result



Product information

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

Beijing Hotgen Biotech Co., Ltd

Add.: 9 building, No.9 Tianfu Street, Daxing District, Beijing, 102600, P.R. China

Website: www.hotgen.com.cn

Coronavirus (2019-nCoV)-Antigentest - Product Photos

