BioWin

CE

Bundesinstitut für Arzneimittel und Medizinprodukte

Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)

For Professional and Self-test Use in Saliva

COVID-19 Antigen

Patients with COVID-19 infection often show the SARS-CoV-2 nucleocapsid protein antigen positive. It is detectable in saliva swab specimen during the acute phase of infection Positive results indicate the presence of viral antigens,but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

Intended use

This product is intended for the qualitative detection of COVID-19 antigen iin saliva swab from suspected individuals of symptomatic or asymptomatic with COVID-19 infection within the first seven days of symptom onset.

Test principle

SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M) and nucleocapsid (N). This Test Kit is a lateral flow chromatographic immunoassay intended for the qualitative detection of the N protein antigen.

Product characteristics

Test sample	Saliva
Short detection time	Rapid detection of novel coronavirus
No instru - mentation required	No need for instruments and equipment, suitable for rapid screening
Detectable for variants	Possess high consistency in the detection of delta and the other variants with the original type

Product information

Product name	Specifications	Storage Conditions
Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	25 tests / box,1 test / unit	4℃-30 ℃

Changzhou Biowin Pharmaceutical Co., Ltd.

Building 3,Caltech port,218 Fumin Road,Changzhou Economic Development Zone,Changzhou,China, CP 29006

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2021/07092021.6

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Changzhou Biowin Pharmaceutical Co., Ltd.
Building 3,Caltech port,218 Fumin Road,
Changzhou Economic Development Zone, Changzhou, China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC on in vitro diagnostics as amended.
From 26 May 2022, manufacturer must fully comply with the IVDR in order to be placed their products in the European market.

The products in Annex I was registered in Spanish MOH with number **RPS/1999/2021**

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Issued on: 07/09/2021

Valid until: 29/03/2022

Authorized Signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

EC REP CERTIFICATE

ANNEX I Medical Device Products

Myoglobin Diagnostic Test Kit (Colloidal Gold)

TroponinI Diagnostic Test Kit(Colloidal Gold)

Disposable Fecal Test Sampler

Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)(For Saliva)

Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)(For Nasal)

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Changzhou Biowin Pharmaceutical Co., Ltd.
Building 3,Caltech port,218 Fumin Road,Changzhou Economic Development Zone,Changzhou,China, CP 29006

CE EC Declaration of Conformity CE

Manufacturer:	Changzhou Biowin Pharmaceutical Co.,Ltd. Add: Building3,Caltech port, 218 Fumin Road, Changzhou Economic Development Zone, Changzhou, China
Whose Single Authorized EU-Representative:	CMC Medical Devices & Drugs S.L. Add: C/Horacio Lengo Nº 18, CP 29006, Málaga-Spain
Product Name:	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) (For Saliva)

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 13641: 2002, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature:
Name:
Title: General manager
Place/Date: China, Sept 3, 2021

Suzhou LQA Standard Certification Co., Ltd.

QUALITY MANAGEMENT SYSTEM CERTIFICATE

This certifies that the Quality Management System of

Changzhou Biowin Biopharm Co., Ltd.

Unified Social Credit Code: **91320405586614439S**

3rd Floor, Building 3, California Technology Port, No.218, Fumin Road,

Changzhou City, Jiangsu Province, P. R. China 213000

Medical devices Quality Management Systems

Requirements for Regulatory Purposes:

YY/T 0287-2017/ISO 13485:2016

Scope of Certification:

Design, Production and Service of In Vitro Diagnostic Reagents

(Within the Scope of Registration)

Certificate Number: **33220M40006R0S**

Certificate Issue Date: **10-Jun-2020**

Initial Registration Date: **10-Jun-2020**

Expiration Date: **09-Jun-2023**

First Surveillance Audit	Second Surveillance Audit

This certificate is valid within the period of the administrative license and qualification prescribed by state;
The certified organization must do the regular surveillance audit, get valid audit conclusion
and add the surveillance identification to maintain the effective of the certificate.

Representative of LQA

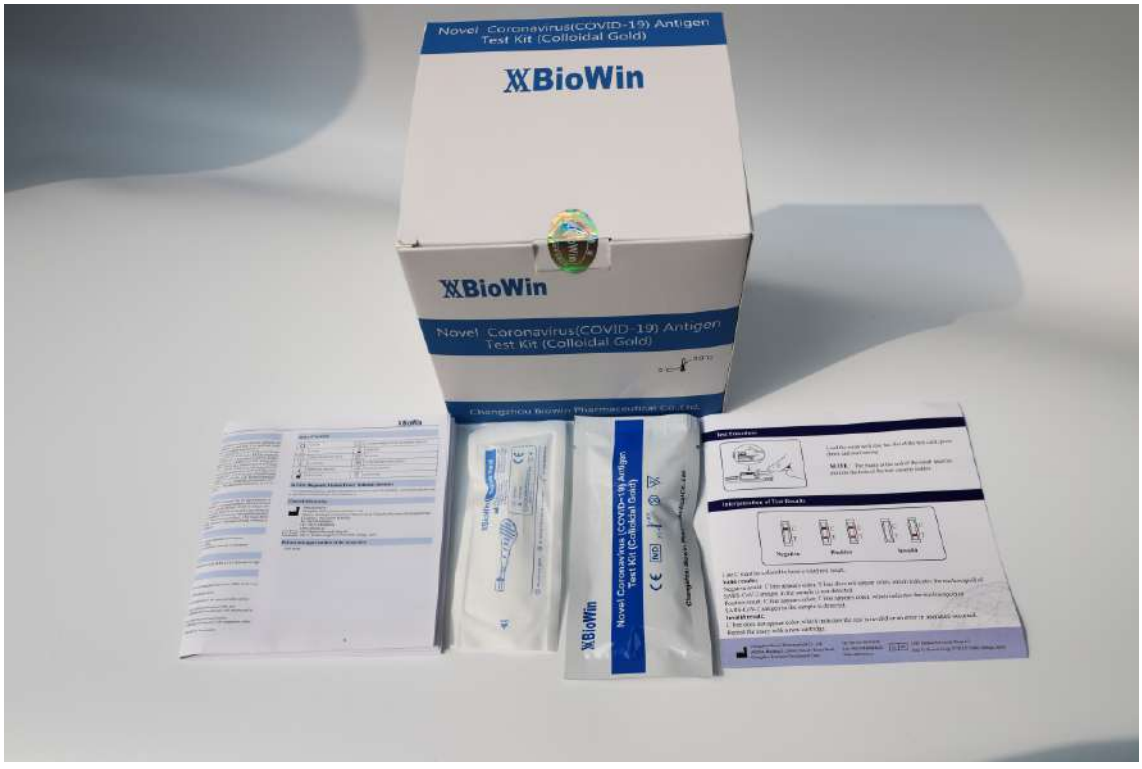
Address: No.209 Zhuyuan Rd. Suzhou City, Jiangsu Province, China(215011)
The Certificate information can be searched on the website of CNCA (www.cnca.gov.cn)

44×44×58

BioWin 新型冠状病毒（COVID-19）抗原 检测试剂盒（胶体金法） Novel Coronavirus（COVID-19） AntigenTest Kit（Colloidal Gold） 常州博闻迪医药股份有限公司 Changzhou Biowin Pharmaceutical Co. Ltd	品　名: 新型冠状病毒（COVID-19）抗原检测试剂盒（胶体金法） Product Name: Novel Coronavirus（COVID-19）AntigenTest Kit（Colloidal Gold） 包装尺寸(CARTON SIZE): 44X44X58CM 毛重(G.W.): KGS 净重(N.W.): KGS 批号(LOT): CE 中国制造 MADE IN CHINA	BioWin 新型冠状病毒（COVID-19）抗原 检测试剂盒（胶体金法） Novel Coronavirus（COVID-19） AntigenTest Kit（Colloidal Gold） 常州博闻迪医药股份有限公司 Changzhou Biowin Pharmaceutical Co. Ltd	品　名: 新型冠状病毒（COVID-19）抗原检测试剂盒（胶体金法） Product Name: Novel Coronavirus（COVID-19）AntigenTest Kit（Colloidal Gold） 包装尺寸(CARTON SIZE): 44X44X58CM 毛重(G.W.): KGS 净重(N.W.): KGS 批号(LOT): CE 中国制造 MADE IN CHINA

Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) Specification list		
铝箔袋尺寸长*宽	length * width	13.5*6.5cm
外花盒尺寸长*宽*高（中盒）	Package box size: length * width * height	14*14*14cm
最大箱每箱36盒（25人份/盒）	Maximum box: 36boxes per box	900Tests
大箱子长*宽*高（大盒/外箱）	Large box size: length * width * height	44*44*58cm
净重	Net weight	11.5kg
毛重	Gross weight	13KG
备注：棒棒糖测试，25人份/盒，多人份的箱规		


BioWin
Novel Coronavirus(COVID-19) Antigen
Test Kit (Colloidal Gold)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XBioWin
Novel Coronavirus(COVID-19) Antigen
Test Kit (Colloidal Gold)
2°C
30°C


XBioWin
Novel Coronavirus(COVID-19) Antigen
Test Kit (Colloidal Gold)
2°C
30°C