

Stock Code: 603387



One Step Test for SARS-CoV-2 Antigen

Introduction



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Brief Introduction of Getein

Product

Product's Name	Specification	Certificates
One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	25 tests/box	CE

Whitelist of Chinese Chamber of Commerce

医保商会推出取得国外标准认证或注册的医疗物资生产企业清单

2020年04月25日 中国医药保健品进出口商会

取得国外标准认证或注册的医疗物资生产企业清单下载			
动态更新 日期: 2020年4月27日			
序号	生产企业	统一社会信用代码	国外注册 认证情况
五、	新型冠状病毒检测试剂 Coronavirus Reagent Test kits		
41	杭州安旭生物科技股份有限公司 Assure Tech (Hangzhou) Co., Ltd.	913301066767726252	欧盟CE认证
42	基蛋生物科技股份有限公司 Getein Biotech, Inc.	913201007360621166	欧盟CE认证
43	江苏美克医学技术有限公司 Jiangsu Medomics Medical Technology Co., Ltd.	91320191MA1RA46X7Q	欧盟CE认证

Package

Packing Specifications:
25 tests/box

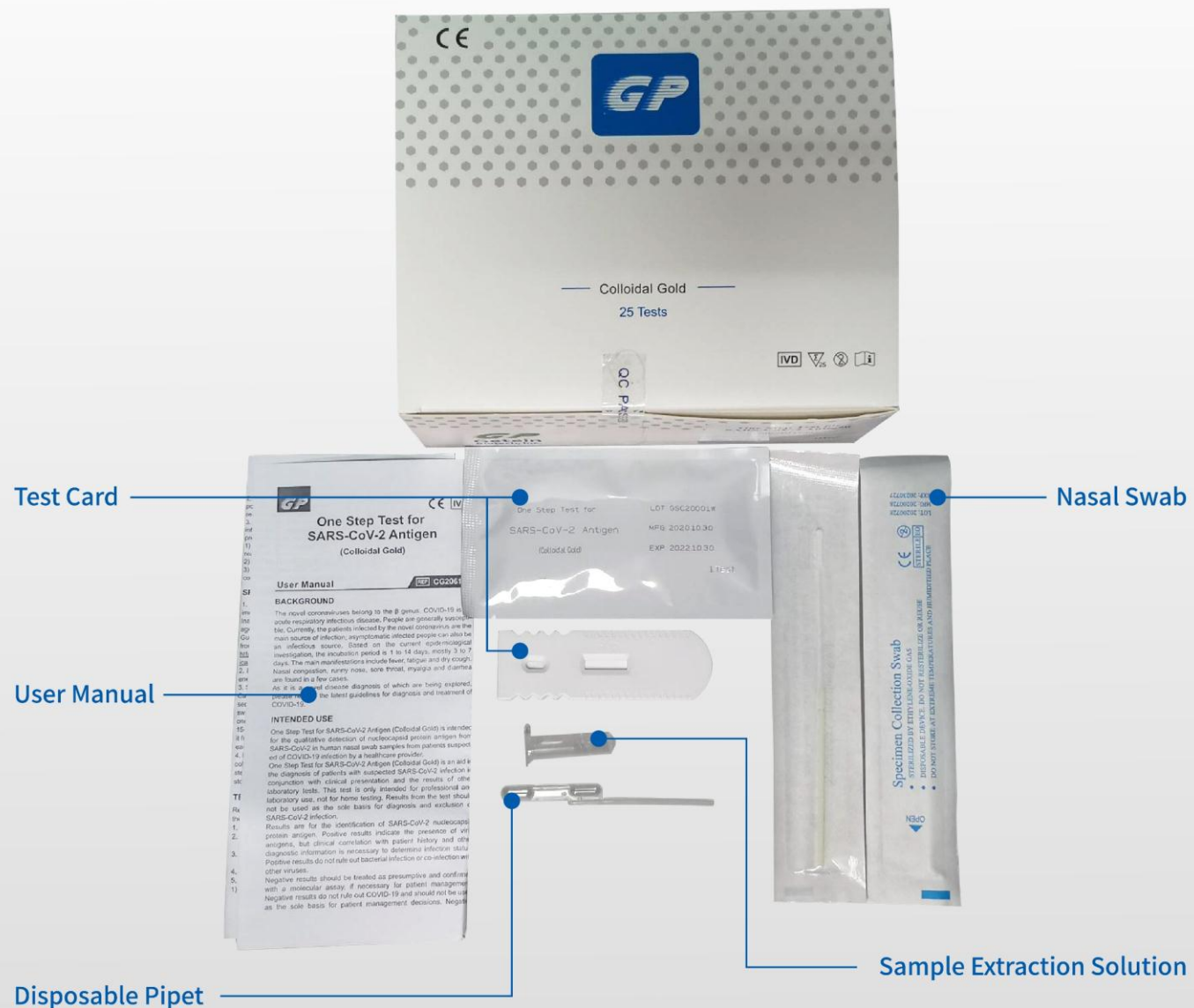
One Box

Dimension: 20*16.5*8cm (1) 0.00264cbm
GW: 0.35kg

One Carton

Dimension: 44*42*35.5cm (1) 0.07cbm
GW: 8.18kg

25tests/box
20 boxes/carton



Test Card

Nasal Swab

User Manual

Disposable Pipet

Sample Extraction Solution



User Manual

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)

User Manual

REF CG2061

BACKGROUND

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

As it is a novel disease diagnosis of which are being explored, please refer to the latest guidelines for diagnosis and treatment of COVID-19.

INTENDED USE

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab samples from patients suspected of COVID-19 infection by a healthcare provider.

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. This test is only intended for professional and laboratory use, not for home testing. Results from the test should not be used as the sole basis for diagnosis and exclusion of SARS-CoV-2 infection.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for patient management decisions. Negative

results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

PRINCIPLE

The test uses recombinant SARS-CoV-2 nucleocapsid protein (N protein) monoclonal antibody I conjugated with colloidal gold coated on the sample pad, and another N protein monoclonal antibody II coated on test line. After the samples has been applied to the test strip, the colloidal gold-labelled recombinant N protein monoclonal antibody I bind with SARS-CoV-2 antigens in sample and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on test line by N protein monoclonal antibody II. The color intensity of each test line increases in proportion to the amount of SARS-CoV-2 antigen in sample.

CONTENTS

1. A kit contains:

Package specifications: 25 tests/box.

- 1) Getein SARS-CoV-2 antigen test card in a sealed pouch with desiccant
- 2) Sample extraction solution: 25 tubes/box
- 3) Sampling swab: 25 pieces/box
- 4) Disposable pipette: 25 pieces/box
- 5) User manual: 1 piece/box

Note: Do not mix or interchange different batches of kits.

2. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad (coated with recombinant SARS-CoV-2 N protein monoclonal antibody I), nitrocellulose membrane with test line (coated with SARS-CoV-2 N protein monoclonal antibody II), the control line (coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

3. Sample extraction solution composition (400 μ L/tube):

Phosphate buffered saline, protein stabilizer and surfactant.

STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months.

Use the test card within 1 hour once the foil pouch is opened.

Store the sample extraction solution at 0-30°C with a valid period of 24 months.

Store the sample extraction solution at 2-8°C for better results.

PRECAUTIONS

1. Do not open pouches until ready to perform the test to protect the test cards from getting damp exposing in air for too long.

2. The test cards can be stored in room temperature with sealed pouches. And the test cards stored in low temperature should reach room temperature before testing.

3. There should be appropriate bio-safety assurance procedure for infectious sources or potential infectious sources. Some relevant precautions are showed below:

- 1) Wear disposable gloves to deal with samples, or sterilize reagents.
- 2) Sterilize spilled samples or reagents with sanitizer.
- 3) Sterilize and cope with all of samples, reagents and potential contaminant with relevant local regulations.

SPECIMEN COLLECTION AND PREPARATION

1. Sample should be **human nasal swab sample**. Test samples immediately after collection for optimal test performance. Inadequate sample collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.htm>

2. It is recommended to use a flocked swab with a PP (polypropylene) rod as a sterile swab for sample collection.

3. Sample collection:

Carefully insert a sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Keep the swab in the nasal cavity for 15-30s, rotate the swab 3 times against the nasal wall then remove it from the nostril. If taking samples from two nostrils, use one swab each.

4. Nasal swab sample should be processed with sample diluent after collection. If testing is delayed, the sample should be stored in a dry, sterilized and strictly sealed plastic tube immediately, it can be stored up to 8 h at 2-8°C before testing.

TEST PROCEDURE

Read the manual carefully before using and operate according to the manual to avoid incorrect results.

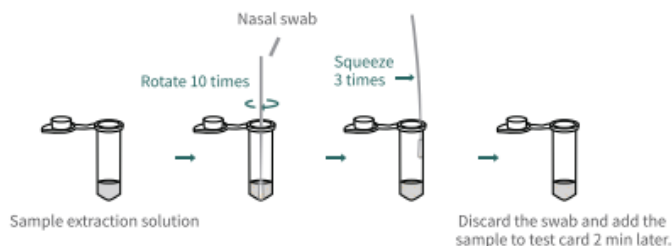
1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature (15-30°C) before test.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Sample pretreatment:
 - 1) Take one tube of sample extraction solution, insert the nasal swab sample into the tube, and rotate the swab 10 times in the

User Manual

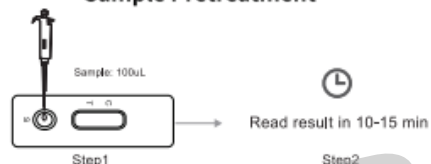
- solution to make the sample dissolve in the sample extraction solution as much as possible.
- 2) Squeeze the swab tip along the inner wall of the sample extraction tube 3 times to keep the liquid in the tube as much as possible before taking it out of the tube.
 - 3) Discard the swab and add the sample to test card 2 min later.
 6. Using sample transfer pipette, deliver **100 μ L** of sample into the sample port on the test card.
 7. Read the result visually in **10-15 min**.

Note:

Don't read results after **20 min**. To avoid confusion, discard the test card after interpreting the result.



Sample Pretreatment



Test

TEST RESULTS

1. Valid Test

Positive (+):

Two bands appear, one at the control area (C) and the other at the test line (T). The result indicates the presence of SARS-CoV-2 antigen.

Negative (-):

A single band appears at the control area (C) and no other band at test line. The result indicates that the sample does not contain SARS-CoV-2 antigen.



Positive



Negative

2. Invalid Test

If no band appears in the control area (C), the test result is invalid. The test should be repeated with a new test card and if the same situation reappears, please stop using this batch of products and contact your supplier.



Note:

1. Positive results indicate the presence of SARS-CoV-2 antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. A positive result does not rule out co-infections with other pathogens.
2. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.

LIMITATIONS

1. The test is for in vitro diagnostic use only.
2. The test results of this kit are for clinical reference only. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment response.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980: 2008 and International Standard ISO 15223-1: 2016.

Key to symbols used

	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		In vitro diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged
	Catalogue number		

Thank you for purchasing One Step Test for SARS-CoV-2 Antigen (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.

Version: WCG93-DX-S-03

Gelein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.bio-GP.com.cn

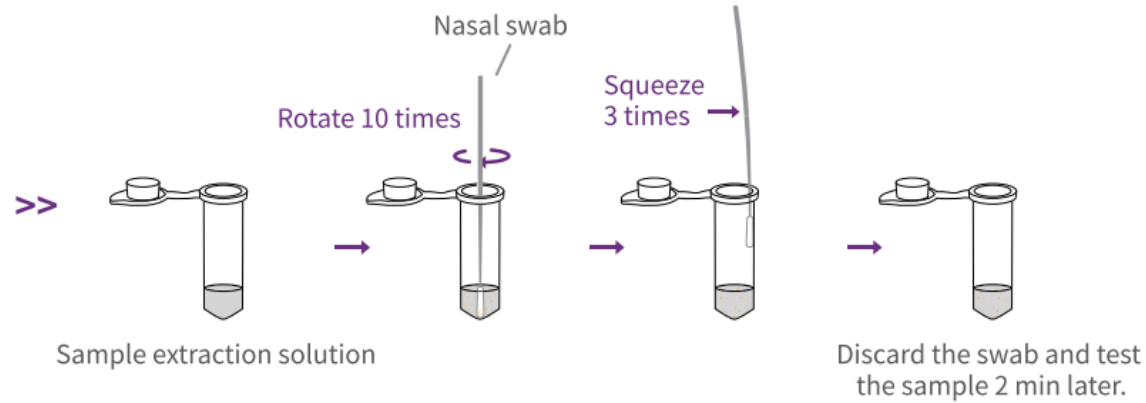
Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

Characteristics

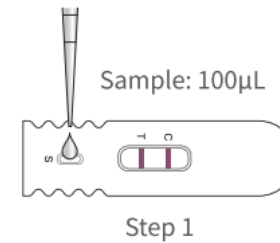
- Specimen type: nasal swab
- Rapid test. The test result is available in 10-15 min.
- Read test results visually. Do not require test equipment.
- Early detection of SARS-CoV-2 infection
- Simple operation and highly-efficient test.

Operation

Sample Pretreatment



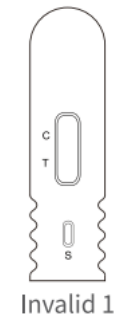
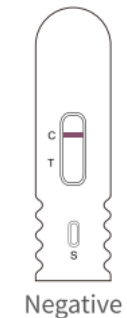
Test >>



⌚
Read result in 10-15 min

Step 2

Test Results



video.

Operation Guide of One Step Test for SARS-CoV-2 Antigen

<https://www.youtube.com/watch?v=0dOYv1hhj1Q>

ISO 13485 Certificate

bsi.



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Getein Biotech, Inc.
No.9 Bofu Road
Luhe District
Nanjing
Jiangsu
211505
China

基蛋生物科技股份有限公司
中国
江苏省
南京市
六合区
沿江工业开发区
博富路9号
邮编: 211505

Holds Certificate No: **MD 728432**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay). Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay).
研发、生产和销售化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂。
研发、生产和销售用于化学发光法试剂，生化试剂，即时诊断（包括胶体金法，免疫荧光法，干式化学法）试剂配套使用的分析仪。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-05-29

Effective Date: 2020-07-26

Latest Revision Date: 2020-07-22

Expiry Date: 2023-07-25



Page: 1 of 1

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780
BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A Member of the BSI Group of Companies.

CE Certificate CIBG



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 3 november 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 28 oktober 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Getein Biotech, Inc met Europees gemachtigde Lotus NL B.V. onderstaand product als in-vitro diagnosticum op de Europese markt te brengen.

Het product staat geregistreerd als in-vitro diagnosticum onder nummer:

**AFP Fast Test Kit (Immunofluorescence Assay),
BNP Fast Test Kit(Immunofluorescence Assay),
CEA Fast Test Kit(Immunofluorescence Assay),
IL-6 Fast Test Kit(Immunofluorescence Assay),
One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)
(geen merknaam) (NL-CA002-2020-54013)**

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermeld product verzoek ik u dit nummer te vermelden. Aan dit nummer kunnen geen verdere rechten ontleend worden, het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel 10, eerste lid van Richtlijn 98/79/EG).

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

Inlichtingen bij:

M.P. Meijer - Michiels

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:

CIBG-20205201

Bijlagen

Uw aanvraag

28 oktober 2020

*Correspondentie uitsluitend
richten aan het retouradres met
vermelding van de datum en
het kenmerk van deze brief.*

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Getein Biotech, Inc de CE-conformiteitsmarkering heeft aangebracht op het desbetreffende product alvorens het in een EU-lidstaat in de handel te brengen. Zodoende garandeert Lotus NL B.V. dat het in-vitro diagnosticum voldoet aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiestelsel.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

CE Certificate Declaration of Conformity

Declaration of Conformity
according to Directive 98/79/EC, on in vitro diagnostic medical devices
Ref. No.:20201103-B01

Maker (Name, Address)	Getein Biotech, Inc. No. 9 Bofu Road, Luhe District, Nanjing, 211505, China		
Authorized Representative (Name, Address)	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.		
Medical device	Product Name	GMDN Code	
	One Step Test for SARS-Cov-2 Antigen (Colloidal Gold)	64787	
Classification	Others		
Applicable coordination standards	EN 13612:2002 EN ISO 18113-1:2011 EN ISO 23640:2015	EN ISO 14971:2012 EN ISO 18113-2:2011 EN ISO 13485:2016	EN ISO15223-1:2016 EN ISO 18113-3:2011 ISO 780:2015

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by BSI Group The Netherlands B. V..

General Manager Enben Su

Nanjing, 3th Nov, 2020
(place and date of issue)


(name and signature or equivalent marking of authorized person)

CE

For Business Use Only

Relevant Certificates

Business License

Foreign Trade Registration Certificate

编号 32010000201804200116

请于每年1月1日至6月30日上网申报上一年度工商年报,逾期未报将被标记为经营异常状态或列入经营异常名录并向社会公示,年报网址见营业执照左下方。





营业执照

(副本)

统一社会信用代码 913201007360621166 (1/1)

名称	基蛋生物科技股份有限公司
类型	股份有限公司(上市)
住所	南京市六合区沿江工业开发区博富路9号
法定代表人	苏恩本
注册资本	13288.9175万元整
成立日期	2002年03月08日
营业期限	2002年03月08日至*****
经营范围	实验、生产或办公设备、配件的研发、生产、销售;生物、生化试剂和实验器材(除许可事项外)的研发、生产、销售;一类、二类、三类医疗器械的研制、生产、销售;三类6840体外诊断试剂的研制、生产、销售;软件的研发、生产、销售;医疗器械和实验、生产或办公设备的租赁、维修;医药、生物、生化科技的技术咨询、技术开发、技术转让和技术服务;自营和代理各类商品及技术的进出口业务(国家限定公司经营或禁止进出口的商品和技术除外)。(依法须经批准的项目,经相关部门批准后方可开展经营活动)



登记机关  2018年04月20日

00072127

企业信用信息公示系统网址: www.jsgsj.gov.cn:58888/province 中华人民共和国国家工商行政管理总局监制

对外贸易经营者备案登记表

统一社会信用代码: 913201007360621166
进出口企业代码: _____

备案登记编号: 02752130

经营者中文名称	基蛋生物科技股份有限公司		
经营者英文名称	Getein Biotech, Inc.		
组织机构代码	经营者类型 (由备案登记机关填写)	其他有限责任公司	
住所	南京市六合区沿江工业开发区博富路9号		
经营场所(中文)	南京市六合区沿江工业开发区博富路9号		
经营场所(英文)	No.9 Bofu Road, Luhe District, Nanjing, 211505, China		
联系电话	025-68568531	联系传真	025-57671919
邮政编码	211505	电子邮箱	gmo@getein.com.cn
工商登记注册日期	2002-3-8	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	苏恩本	有效证件号	32010619660305045X
注册资金	壹亿叁仟贰佰捌拾捌万玖仟壹佰柒拾伍元	(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

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、盖章。

 2018年06月08日

Product Registration of Ministry of Health in EU

Registro de Responsables de Productos Sanitarios - RPS/368/2020

Datos de la notificación

Datos de registro

Nº Registro: RPS/368/2020 Fecha Registro: 23/03/2020

Datos del Responsable

Tipo de Responsable (*): Rep. Autorizado Tipo de entidad: Empresa

CIF (*): B93316149 Nombre (*): CMC MEDICAL DEVICES & DRUGS S.L.

Dirección (*): C/ HORACIO LENGU Nº 18

Localidad (*): MÁLAGA

Provincia (*): Málaga CP (*): 29006

Teléfono (*): 951214054 Fax:

e-mail (*): info@cmcmedicaldevices.com Web:

Datos del Fabricante

Nombre o Razón Social (*): Getein Biotech, Inc.

Dirección (*): No.9 Bofu Road, Luhe District, 211505, Nanjing, China

Localidad (*): Nanjing

País (*): República Popular China CP:

Teléfono (*): 00862568568508 Fax:

e-mail (*): tech@getein.com.cn Web:

Datos de Productos Comunicados

Estatus (*): Primera Comunicación

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila.

Nombre Comercial	Tipo de Producto	Estado del producto	Acción
SINGLE USE MEDICAL FACE MASK	Clase I	Primera Comunicación	

Medical Device Production License



STOCK CODE 603387



Comprehensive Solution of Laboratory Testing for COVID-19

For Better Control of the COVID-19 Pandemic

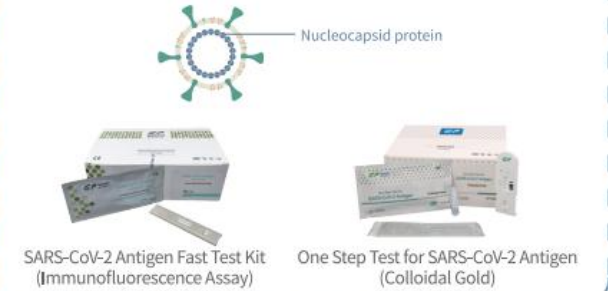


Getein SARS-CoV-2 Testing Products

Nucleic Acid Test



Antigen Test



Novel Coronavirus (2019-nCoV) IgM/IgG antibody Fast Test Kit (Immunofluorescence Assay)



Quantitative Detection

One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)



Qualitative Detection

Antibody Test



Nucleic Acid Test



Antigen Test



Antibody Test

video.

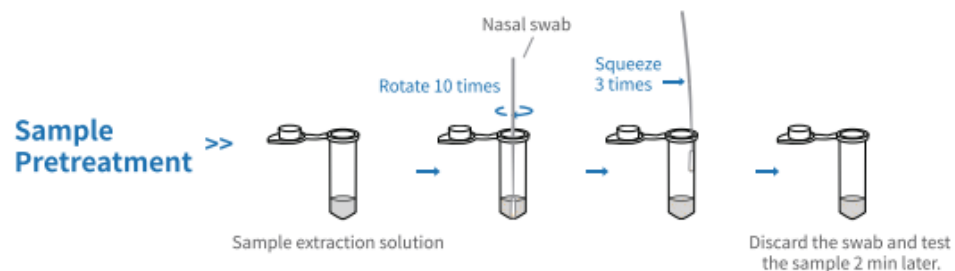
Production Line for Novel Coronavirus (2019-nCoV) Tests

<https://www.youtube.com/watch?v=wn4pji7sluA>

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)

- Read test results visually. Do not require test equipment.

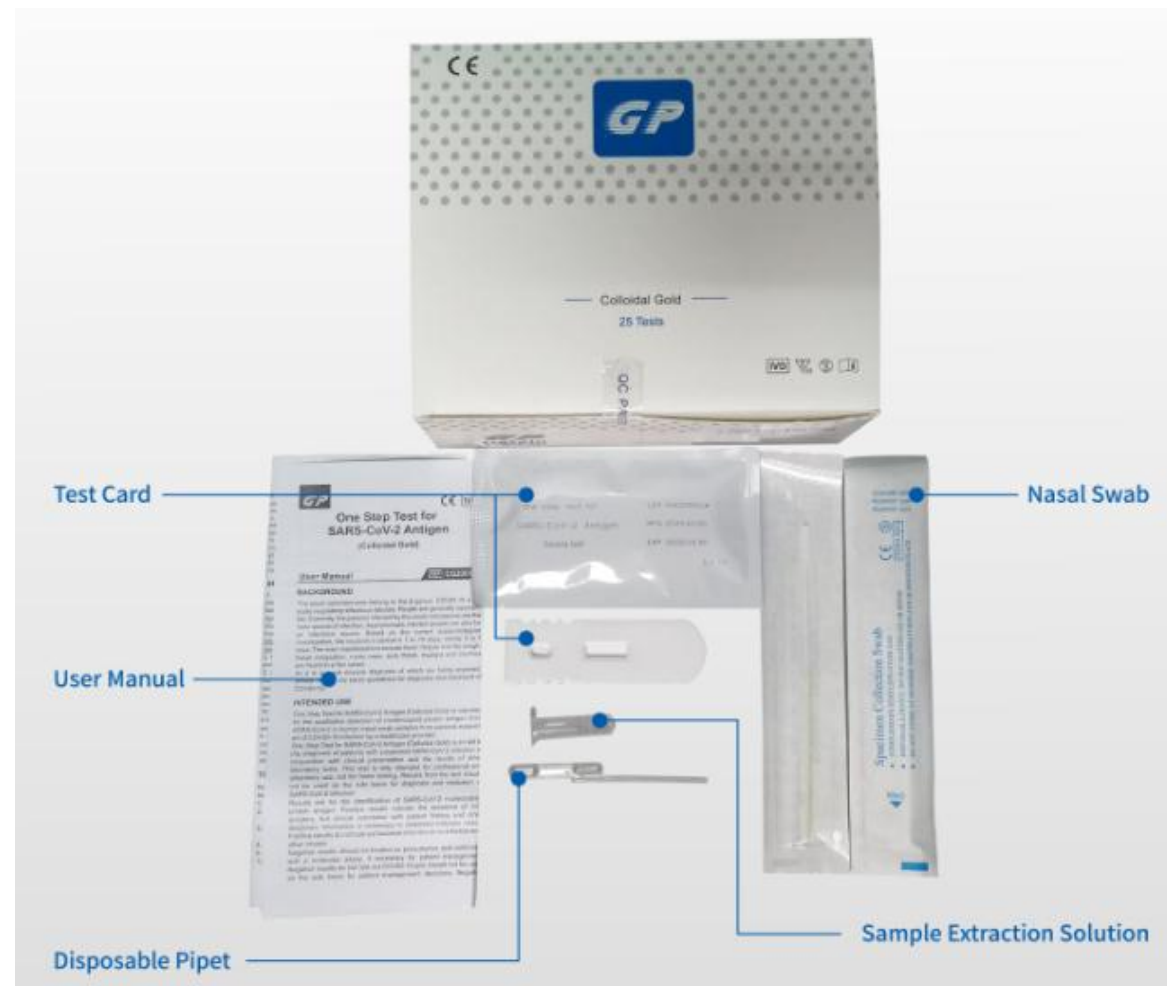
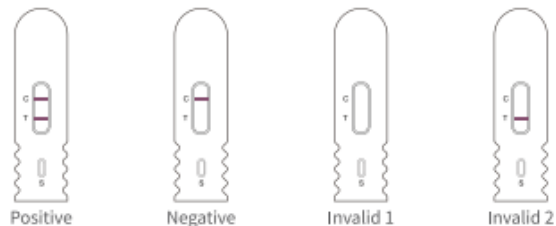
Operation



Test



Test Results



video.

Operation Guide of One Step Test for SARS-CoV-2 Antigen

<https://www.youtube.com/watch?v=0dOYv1hhj1Q>

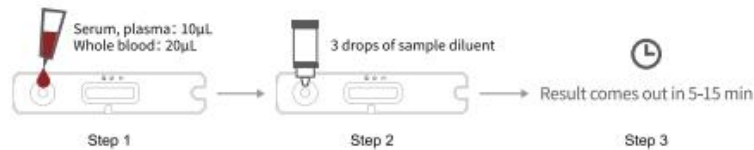
Antibody Test of SARS-CoV-2

CE Marked

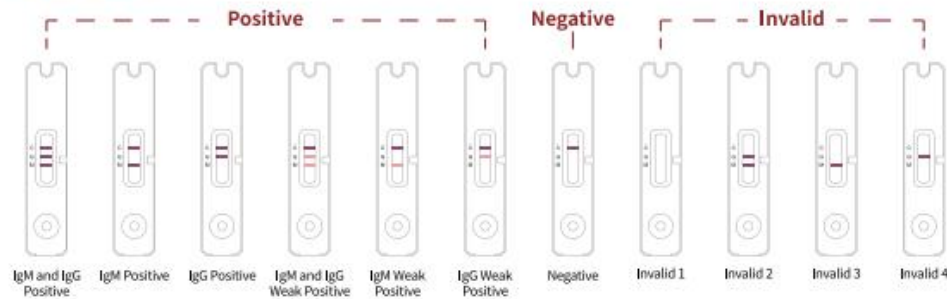
One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)

- Result in 5-15 min visually. Do not require test equipment.
- Sample type: whole blood/serum/plasma

Operation >>



Test Result >>



video.

Operation Guide for testing 2019-nCoV IgM/IgG antibody

<https://www.youtube.com/watch?v=T97UrjPbhgl>

2019-nCoV Nucleic Acid Detection One-Stop Solution

Getein 2019-nCoV Nucleic Acid Detection Solution



COVID-19 Molecular Testing through Real-time RT-PCR

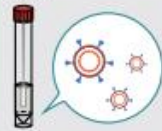
1. Collecting Sample

A nasopharyngeal or oropharyngeal swab collects a mucus sample for testing.



2. Sample Preservation

The swab is immersed in sample preservation solution, which deactivates the virus and keeps the virus nucleic acid stable.



Freshly collected samples should be stored at 2 – 8 °C for up to 48 h or proceeded to RNA extraction.

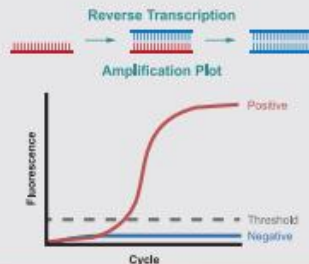
3. RNA Extraction

Purified RNA is extracted from deactivated 2019-nCoV viral specimen.

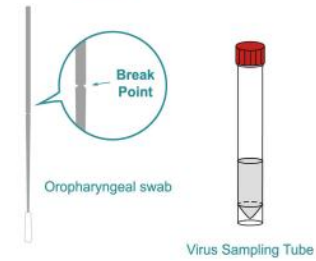


4. Real-time RT-PCR

Purified RNA is reverse-transcribed to cDNA and amplified by PCR.



Disposable Virus Sampling Tube



Nucleic Acid Extraction

Intended Use

The product is intended use the extraction and purification of viral nucleic acids (DNA and RNA) in samples.



Novel Coronavirus (2019-nCoV) Real-time RT-PCR Kit



Gold Standard

Direct Detection of the Presence of 2019-nCoV RNA



Room Temperature Transportation

video.
2019-nCoV Real-time RT-PCR Kit Test Procedure
<https://www.youtube.com/watch?v=X363CCMHsxo>