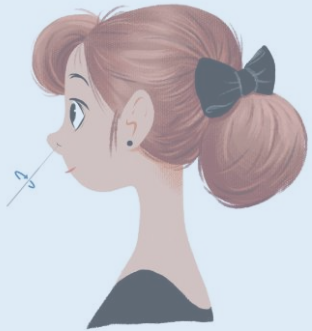
新型冠状病毒（SARS-CoV-2）抗原检测试剂盒（胶体金法）
One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)

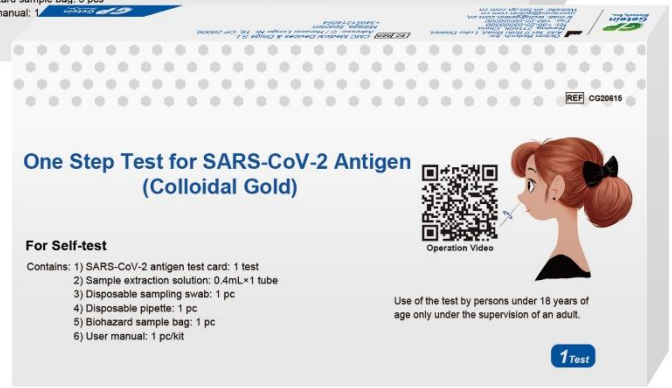


✔ 家用自测 For self-test

✔ 医用 For professional use

产品图片
Product Pictures

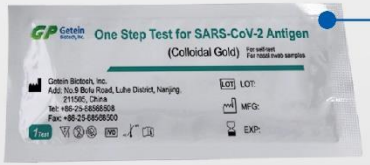
家用自测 For Self-Test



Getein Biotech, Inc. | STOCK CODE 603387

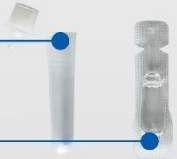
User Manual

SARS-CoV-2 Antigen Test Card



Biohazard Sample Bag

Disposable Pipette



Disposable Sampling Swab

Sample Extraction Solution

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产品规格
Specifications

试剂盒及包装箱规格信息
Info. of the Test Kit and Export Packing Cartons

产品名称 Product Name	用途 Use	产品规格 Specifications	试剂盒尺寸 Size (cm)	试剂盒重量 Weight/Kit (g)	包装箱规格 Kit Quantity/Carton	包装箱尺寸 Size of Carton (cm)	包装箱重量 Weight per Carton (kg)
新型冠状病毒（SARS-CoV-2）抗原检测试剂盒（胶体金法） One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	家用自测 For Self-Test	1人份 1 Test/Kit	7*1.8*13 cm	25.5 g	300 盒/箱 300 Kits/Carton	49.5*40.5*30 cm	8.6 kg/箱 8.6 kg/Carton
		5人份 5 Tests/Kit	7*5.3*13 cm	76.6 g	120 盒/箱 120 Kits/Carton	55.5*41*30 cm	10.44 kg/箱 10.44 kg/Carton
	医用 For Professional Use	25人份 25 Tests/Kit	20*16*6.5 cm	322 g	24 盒/箱 24 Kits/Carton	44*42*35.5 cm	8.91 kg/箱 8.91 kg/Carton

部分包装纸箱展示 Display of the Export Packing Cartons

Packing carton for 5 T/kit (Self-Test)
Size: 55.5*41*30 cm

Packing carton for 1 T/kit (Self-Test)
Size: 49.5*40.5*30 cm

产品彩页
Brochure

STOCK CODE 603387

Getein Biotech, Inc.

One Step Test for SARS-CoV-2 Antigen

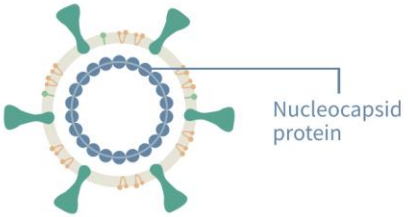
(Colloidal Gold)

- For self-test

Rapid, Convenient, Easy and Reliable Detection of COVID-19

Intended Use

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 antigens in human nasal swab samples.
This test is suitable for medical laypersons as a self-test at home or at work.



Product Components

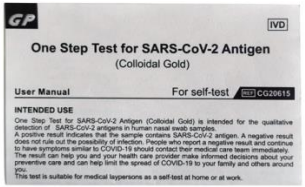
SARS-CoV-2 antigen test card

Sample extraction solution

Disposable pipette

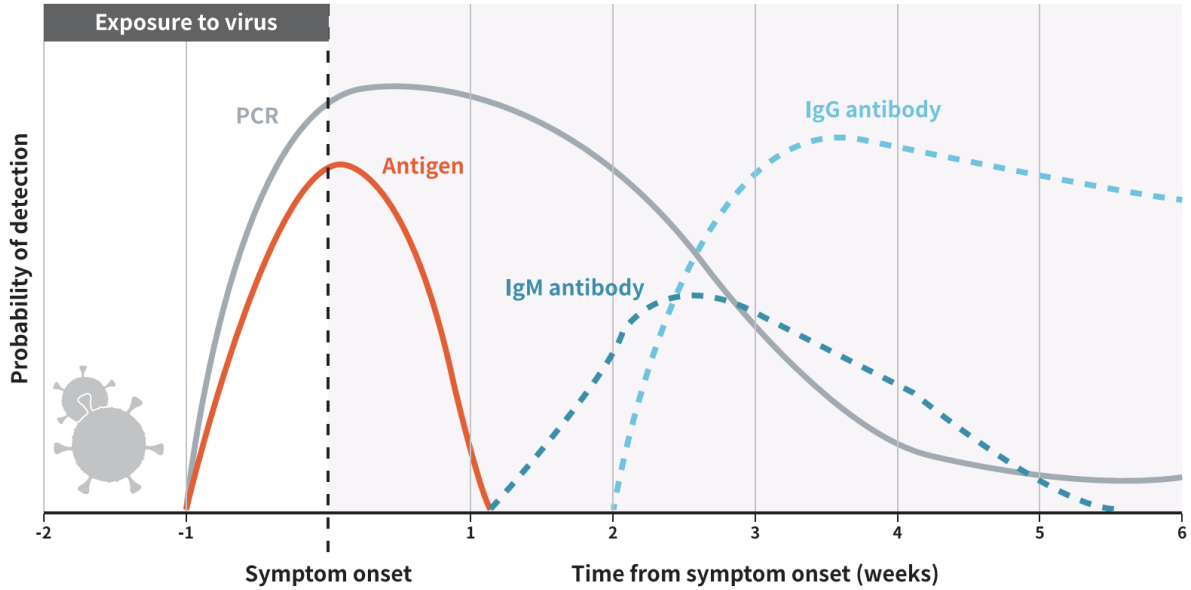
Biohazard sample bag

Disposable sampling swab



User manual

COVID-19 Diagnostic Testing



PCR-based tests can detect small amounts of viral genetic materials.

Antigen tests detect the presence of viral proteins and can return positive results when a person is most infectious.

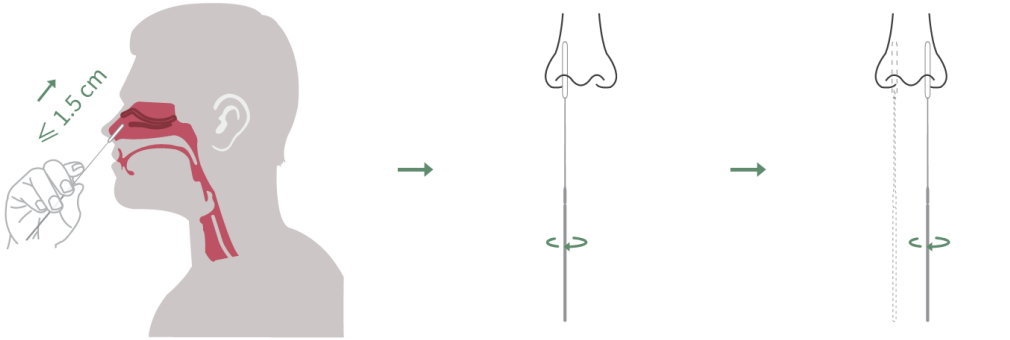
Antibody tests detect the body' s immune response to the virus.

Features

- Non-invasive sampling (Sample type: nasal swab)
- Rapid test. Test result available in 10-15 min.
- Read test results visually. Do not require test equipment.
- Simple operation, easy to learn and use
- Early detection of SARS-CoV-2 infection
- Room temperature storage (4-30°C)

Operation

Nasal Swab Sampling >>

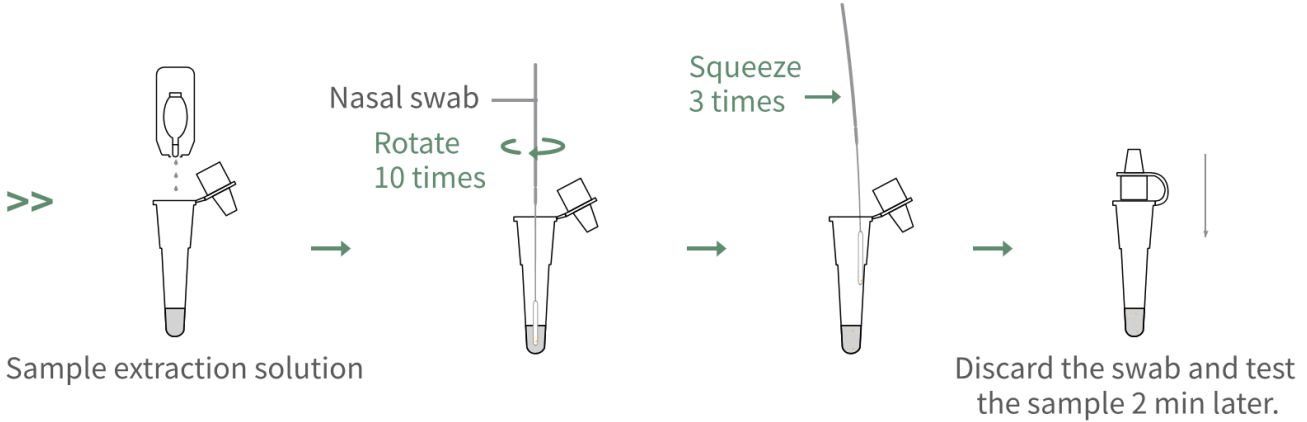


Insert the collection tip of swab into one nostril.

Rotate ⩾ 4 times (15 s in total)

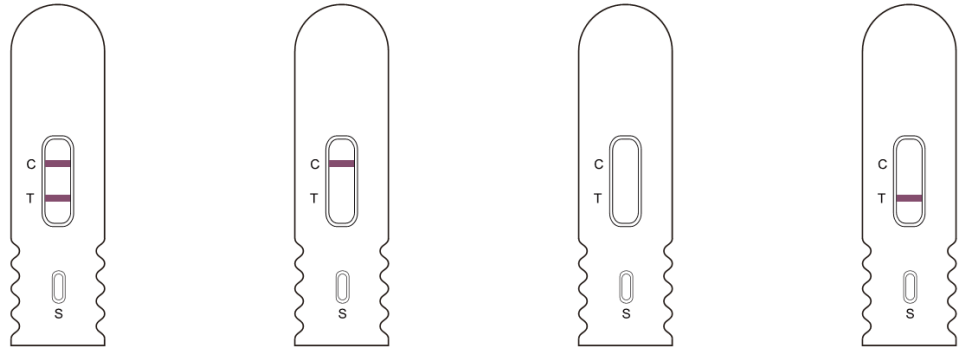
Repeat with the same swab.

Sample Pretreatment >>



Test >>

Test Results



Scan the QR code to get operation video

医用 For Professional Use

STOCK CODE 603387

Getein Biotech, Inc.

One Step Test for SARS-CoV-2 Antigen

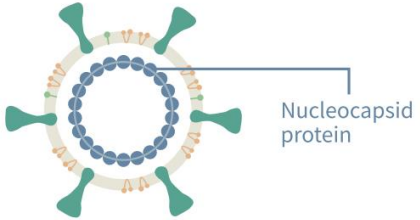
(Colloidal Gold)

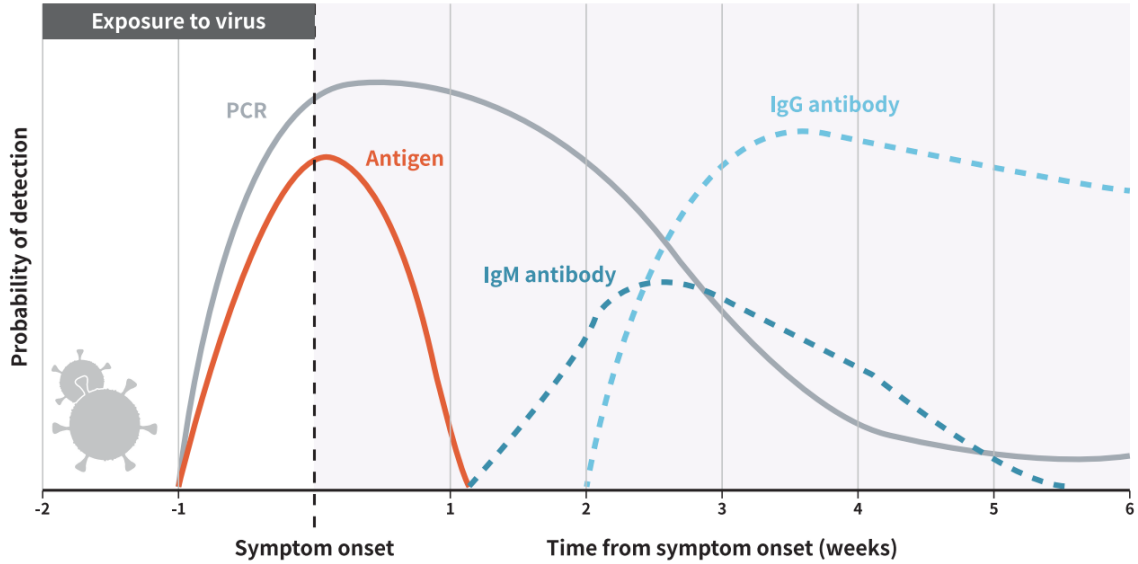
CE Marked

Rapid, Reliable, Early and Easy Detection of COVID-19

Intended Use

The test kit is intended for qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab sample from patients suspected of COVID-19 infection by a healthcare provider.





PCR-based tests can detect small amounts of viral genetic materials.

Antigen tests detect the presence of viral proteins and can return positive results when a person is most infectious.

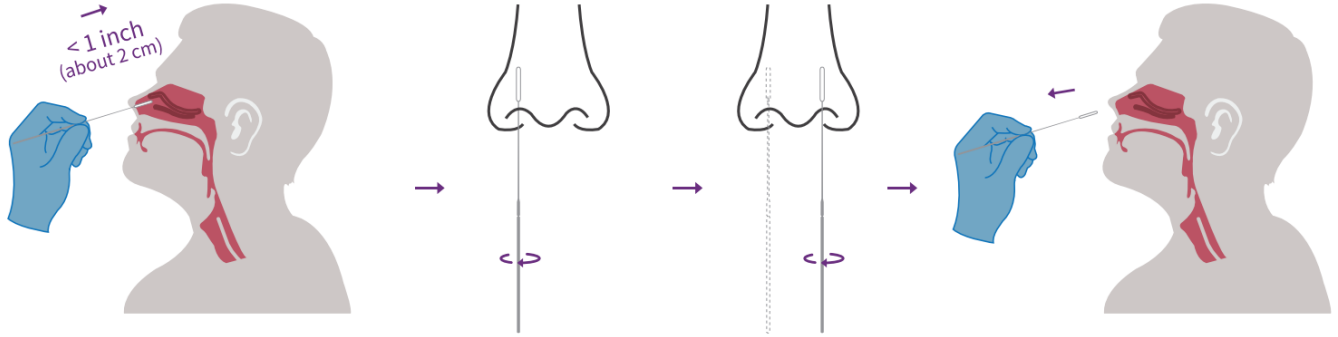
Antibody tests detect the body' s immune response to the virus.

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

Nasal Swab Sampling >>



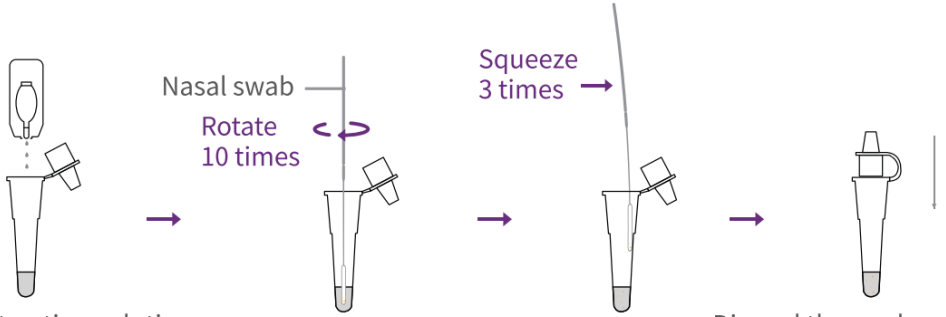
Tilt head back 70°.
Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch (about 2 cm) into the nostril).

Stay for 15-30 s, then rotate 3 times against the nasal wall

Change to another nostril if needed

Remove

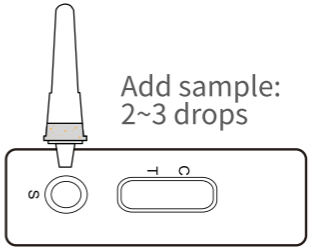
Sample Pretreatment >>



Sample extraction solution

Discard the swab and test the sample 2 min later.

Test >>

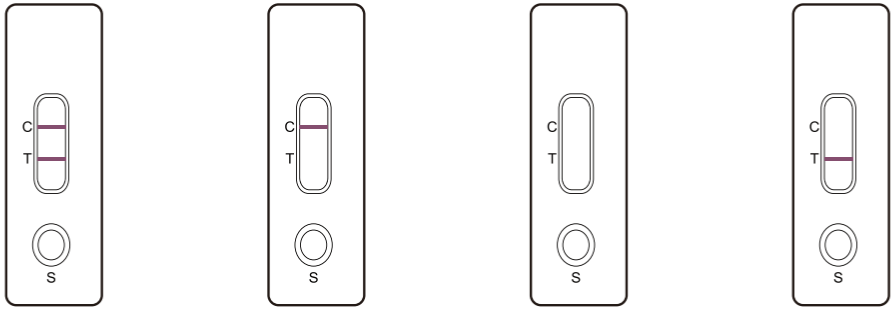


Step 1

Read result in 10-15 min

Step 2

Test Results



Positive | Negative | Invalid 1 | Invalid 2

04

产品说明书
User Manual

家用自测
For Self-Test

IVD

One Step Test for SARS-CoV-2 Antigen

(Colloidal Gold)

User Manual For self-test REF CG20615

INTENDED USE

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 antigens in human nasal swab samples.
A positive result indicates that the sample contains SARS-CoV-2 antigen. A negative result does not rule out the possibility of infection. People who report a negative result and continue to have symptoms similar to COVID-19 should contact their medical care team immediately.
The result can help you and your health care provider make informed decisions about your preventive care and can help limit the spread of COVID-19 to your family and others around you.
This test is suitable for medical laypersons as a self-test at home or at work.

WHEN TO USE A TEST KIT?

Use this test:
- If you want to test yourself.
- If you have symptoms similar to COVID-19, such as: E.g. headache, fever, cough, sore throat, loss of the sense of smell or taste, shortness of breath, muscle pain.
- If you are concerned that you have come into contact with Covid-19.
- Use of the test by persons under 18 years of age only under the supervision of an adult.

Do not use this test:
- ✕ Without adult supervision if you are under 18 years of age
- ✕ If you are prone to nosebleeds

Warnings and Precautions

- Only used for in vitro diagnostics. Please read the instructions for use carefully before use.
- Do not use this test as the only guide to managing your illness. If your symptoms persist or worsen, or if at any time you are concerned, please contact a doctor.
- Always keep out of the reach of children. Small parts of the kit can be a choking hazard.
- Do not use this product after the expiration date.
- Only use the test components supplied. Do not replace the extraction reagent with any other liquid.
- Do not perform the test in direct sunlight.
- Avoid contact with the extraction reagent.
- This test takes a sample from inside the nose. Follow the user manual carefully when performing the test. Taking sample incorrectly can lead to inaccurate test results.
- The test card must remain in the sealed pouch until use.
- All samples are to be regarded as potentially dangerous and treated like infectious material.
- The used test kit must be disposed of in accordance with federal, state and local regulations.

CONTENTS

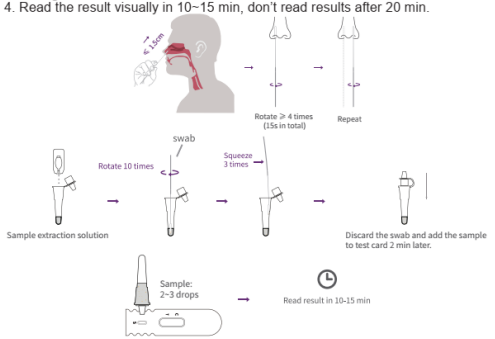
1. A kit contains:
Package specifications: 1 T/kit, 3 T/kit, 5 T/kit.
1) SARS-CoV-2 antigen test card
2) Sample extraction solution
3) Disposable sampling swab
4) Disposable pipette
5) Biohazard sample bag
6) User manual: 1 piece/kit
Additional required materials: clock, timer or stopwatch
Note: Do not mix or interchange different batches of kits.

PREPARING THE TEST

- Read the entire instructions for use carefully before starting the test. Take the time to be calm and conscientious execution.
- Check out the training video at:
- Make sure that all test components are at room temperature.
- The clock, timer or stop watch must be within reach.
- Make sure that the packaging is intact. Use only undamaged packaging.
- Before performing the test, wash your hands with soap and water and dry them thoroughly.
- Do not open the foil packaging until you are ready to perform the test. Use the test device within 1 hour of opening.

TEST PROCEDURE

1. Gently insert the entire collection tip of the swab into one nostril, but do not insert the swab more than 1.5 cm into your nose. Using medium pressure, rotate the swab slowly in a circular motion around the inside wall of your nostril at least 4 times for a total time of 15 seconds. Repeat the same process with the same swab in the other nostril.
2. Pour one tube of sample extraction solution into the disposable pipette, insert the swab after sampling to the disposable pipette and rotate the swab 10 times in the solution to make the sample dissolve in the sample extraction solution as much as possible.
   Squeeze the swab tip along the inner wall of the disposable pipette 3 times to keep the liquid in the disposable pipette as much as possible before taking it out. Discard the swab and tighten the disposable pipette.
3. Place the test card horizontally on a clean surface. Add 2~3 drops of sample by disposable pipette to test card 2 min later. Nasal swab sample should be processed with sample extraction solution after collection. If testing is delayed, the sample should be strictly sealed, it can be stored up to 8 h at 2~8°C before testing.
4. Read the result visually in 10~15 min, don't read results after 20 min.



DISPOSAL THE SAMPLE AND CLEAN-UP

1. Place disposable virus sampling swab, sample extraction solution, disposable pipette and the test card in the biohazard specimen bag and seal the bag.
2. Throw away the remaining sample kit items.
3. Re-apply hand sanitizer.

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 or the concentration is below the limit of detection of the kit.

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.

FREQUENTLY ASKED QUESTIONS

• When can I test myself?
You can always test yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated according to the regulations of the responsible authorities.
• What should I pay attention to in order to obtain the most exact test result possible?
Always follow the instructions for use exactly. Perform the test immediately after collecting the sample. Using disposable pipette, deliver 2~3 drops of sample into the sample port on the test card. Too many or too few sample can lead to an incorrect or invalid test result.
• The test strip is very discolored. What is the reason or what am I doing wrong?
The indicator strip can only hold a limited amount of liquid. 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.
• My result is positive. What should I do?
If a horizontal colored line is visible in the control area (C) as well as in the test area (T), your result is positive and you should immediately contact the medical facility in accordance with the requirements of your local authorities. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Your test result may be checked and the next steps will be explained to you.
• My result is negative. What should I do?
If only a horizontal colored line is visible in the control area (C), this may mean that you are negative or that the viral load is too low to be recognized by the test. Negative results can not rule out COVID-19 and should not be used as the sole basis for patient management decisions. It should be considered in the context of your recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. If you experience symptoms such as fever, fatigue and dry cough, nasal congestion, runny nose, sore throat, myalgia and diarrhea, contact the nearest medical facility applying the regulations of your local authority. In addition, you can repeat the test with a new test kit.

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.

PRINCIPLE

The test uses anti-SARS-CoV-2 nucleocapsid protein (N protein) monoclonal antibody I conjugated with colloidal gold coated on the sample pad, and another anti-SARS-CoV-2 N protein monoclonal antibody Ⅱ coated on test line. After the

samples have been applied to the test strip, the colloidal gold-labelled anti-SARS-CoV-2 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 anti-SARS-CoV-2 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.

PERFORMANCE CHARACTERISTICS

1 Analytical sensitivity -- Limit of Detection (LoD)
The LoD for nasal swab were established using heat-inactivated SARS-CoV-2 isolate strain. The strain was spiked into the pooled human nasal swab matrix obtained from multiple healthy volunteers eluted in VTM and confirmed as SARS-CoV-2 negative by RT-PCR to prepare positive samples. The estimated LoD found from the initial two-fold serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for nasal swab was 200 $TCID_{50}$/mL.

2 Clinical Agreement Study
The clinical performance of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) was evaluated by testing a total of 480 nasal swab samples. It is compared to the results of RT-PCR assays. Overall study results were shown in the tables below.

Total		BGI's RT-PCR kit		
		positive	negative	Subtotal
Getein's kit	positive	165	4	169
	negative	5	306	311
	Subtotal	170	310	480

Positive percent agreement (Diagnostic sensitivity) = 165 / (165 + 5) ×100% = 97.06% (95% CI: 93.30%-98.74%)
Negative percent agreement (Diagnostic specificity) = 306 / (306 +4) × 100% = 98.71% (95% CI: 96.73%-99.50%)
Total percent agreement = (165 + 306) / 480 × 100% = 98.13% (95% CI: 96.48%-99.01%)

3 Analytical Specificity
3.1 Cross-Reactivity & Microbial Interference
Each organism and virus were tested in triplicate in the absence and presence of SARS-CoV-2 respectively. According to the test results, there was no cross-reactivity with the following viruses or organisms.

Viruses or organisms	Concentration
Human coronavirus 229E	1 x 10^5 PFU/mL
Human coronavirus OC43	1 x 10^5 PFU/mL
Human coronavirus NL63	9.87 x 10^3 PFU/mL
MERS coronavirus	7930 PFU/mL
Adenovirus (e.g. C1 Ad. 71)	1 x 10^5 PFU/mL
Human Metapneumovirus (hMPV)	1 x 10^5 PFU/mL
Parainfluenza virus Type 1	1 x 10^5 PFU/mL
Parainfluenza virus Type 2	1 x 10^5 PFU/mL
Parainfluenza virus Type 3	1 x 10^5 PFU/mL
Parainfluenza virus Type 4a	1 x 10^5 PFU/mL
Influenza A	1 x 10^5 PFU/mL
Influenza B	2.92 x 10^4 PFU/mL
Enterovirus	1 x 10^5 PFU/mL
Respiratory syncytial virus	1 x 10^5 PFU/mL
Rhinovirus	4.17 x 10^5 PFU/mL
Haemophilus influenzae	1 x 10^6 CFU/mL
Streptococcus pneumoniae	1 x 10^6 CFU/mL
Streptococcus pyogenes	1 x 10^6 CFU/mL
Candida albicans	1 x 10^6 CFU/mL
Bordetella pertussis	1 x 10^6 CFU/mL
Mycoplasma pneumoniae	1 x 10^6 CFU/mL
Chlamydia pneumoniae	1 x 10^6 CFU/mL
Legionella pneumophila	1 x 10^6 CFU/mL
Mycobacterium tuberculosis	1 x 10^6 CFU/mL
Pneumocystis jirovecii	1 x 10^6 CFU/mL
Pseudomonas Aeruginosa	1 x 10^6 CFU/mL
Staphylococcus Epidermidis	1 x 10^6 CFU/mL
Streptococcus Salivarius	1 x 10^6 CFU/mL

3.2 Interferences
The potentially interfering substances that may be found in the upper respiratory tract in symptomatic subjects (including over the counter medications). These interfering substances were dissolved with normal saline to obtain a high concentration. Nasal swab samples spiked with/without SARS-CoV-2 at 3×LoD were added with the below high levels of potentially interfering substances. No false positive or false negative results were seen at the following concentrations.

Potentially Interfering Substances	Concentration
Blood (human)	5%
Mucin	5 mg/mL
Naso GEL (NeilMed)	5% v/v
CVS Nasal Drops (phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam Cold Remedy	5% v/v
Homeopathic (Alkalol)	10 % v/v
Sore Throat PhenolSpray	15% v/v
Tobramycin	3.3 mg/dL
Mupirocin	0.15 mg/dL
Fluticasone	5%v/v
Tamiflu (Oseltamivir phosphate)	500 mg/dL
Biotin	0.35 mg/dL
Methanol	0.15%w/v
Diphenhydramine	0.0774 mg/dL
Dextromethorphan	0.00156 mg/dL
Dexamethasone	1.2 mg/dL

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 shored 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.

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 detail in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	In vitro diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
	Keep away from sunlight		Do not use if package is damaged
REF	Catalogue number		Keep away from rain

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.


Getein 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: en.bio-gp.com.cn

EC REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

Version: WCG93-DXF-S-01
Last Edition:15/04/2021

医用
For
Professional
Use

CE IVD

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 investi0 gation, 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 anti-SARS-CoV-2 nucleocapsid protein (N protein) monoclonal antibody I conjugated with colloidal gold coated on the sample pad, and another anti-SARS-CoV-2 N protein monoclonal antibody Ⅱ coated on test line. After the samples have been applied to the test strip, the colloidal gold-labelled anti-SARS-CoV-2 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 anti-SARS-CoV-2 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: 1 test/box,3 tests/box,5 tests/box,7 tests/box,10 tests/box,14 tests/box,25 tests/box.

1) Getein SARS-CoV-2 antigen test card in a sealed pouch with desiccant
2) Sample extraction solution
3) Sampling swab
4) Disposable pipette
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 anti-SARS-CoV-2 N protein monoclonal antibody Ⅰ), nitrocellulose membrane with test line (coated with anti-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 μL/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 shored 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.html
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 the same sampling swab.
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

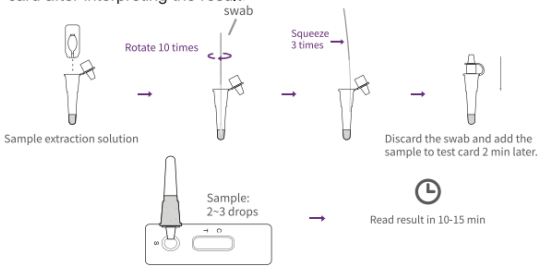
Read the manual carefully before using and operate according to the manual to avoid incorrect results.

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) Pour one tube of sample extraction solution into the disposable pipette, insert the nasal swab sample into the disposable pipette and rotate the swab 10 times in the 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 disposable pipette 3 times to keep the liquid in the disposable pipette as much as possible before taking it out. Discard the swab and tighten the disposable pipette.
   3) Place the test card horizontally on a clean surface. Add 2~3 drops of sample by disposable pipette to test card 2 min later.
6. 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.



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.

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 detail in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	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-DXE1-S-01

Getein 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: en.bio-gp.com.cn

EC REP Lotus NL B.V.
Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com
Tel: +31644168999

资质认证及临床评估
Certificates and Clinical Evaluation

基蛋生物新冠检测试剂被列入中国出口白名单
Getein COVID-19 Test Kits on the Export Whitelist of China

生产企业	统一社会信用代码	国外注册认证情况	省份	产品型号
基蛋生物科技股份有限公司 Getein Biotech, Inc.	91320100736062116 6	CE	Jiangsu Province	One Step Test for Novel Coronavirus(2019-nCoV) IgG antibody (Colloidal Gold) One Step Test for Novel Coronavirus(2019-nCoV) IgM antibody (Colloidal Gold) One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold) Novel Coronavirus (2019-nCoV) Real-time RT-PCR Kit Akso SARS-CoV-2 Real-time RT-PCR Kit SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay) One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) One Step Test for SARS-CoV-2 Total Antibody/Neutralizing Antibody (Colloidal Gold) One Step Test for FluA/FluB/SARS-CoV-2 Antigen (Colloidal Gold) SARS-CoV-2 Total Antibody/Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay) FluA/FluB/SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay) FluA/FluB/SARS-CoV-2 Real-time RT-PCR Kit SARS-CoV-2/VOC-202012/01 Real-time RT-PCR Kit SARS-CoV-2/501.V2 Real-time RT-PCR Kit Novel Coronavirus(2019-nCoV) IgM/IgG antibody Fast Test Kit (Immunofluorescence Assay)

CE 认证

CE Certificate

Declaration of Conformity

according to Directive 98/79/EC, on in vitro diagnostic medical devices

Ref. No.:20210124-A01

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.	
	Product Name	**GMDN Code**
Medical device	One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)	64756
	One Step Test for SARS-Cov-2 Antigen (Colloidal Gold)	64787
Classification	Others	

Applicable coordination standards	EN 13612:2002	EN ISO 14971:2012	EN ISO15223-1:2016
	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
	EN ISO 23640:2015	EN ISO 13485:2016	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, 24th Jan. 2021

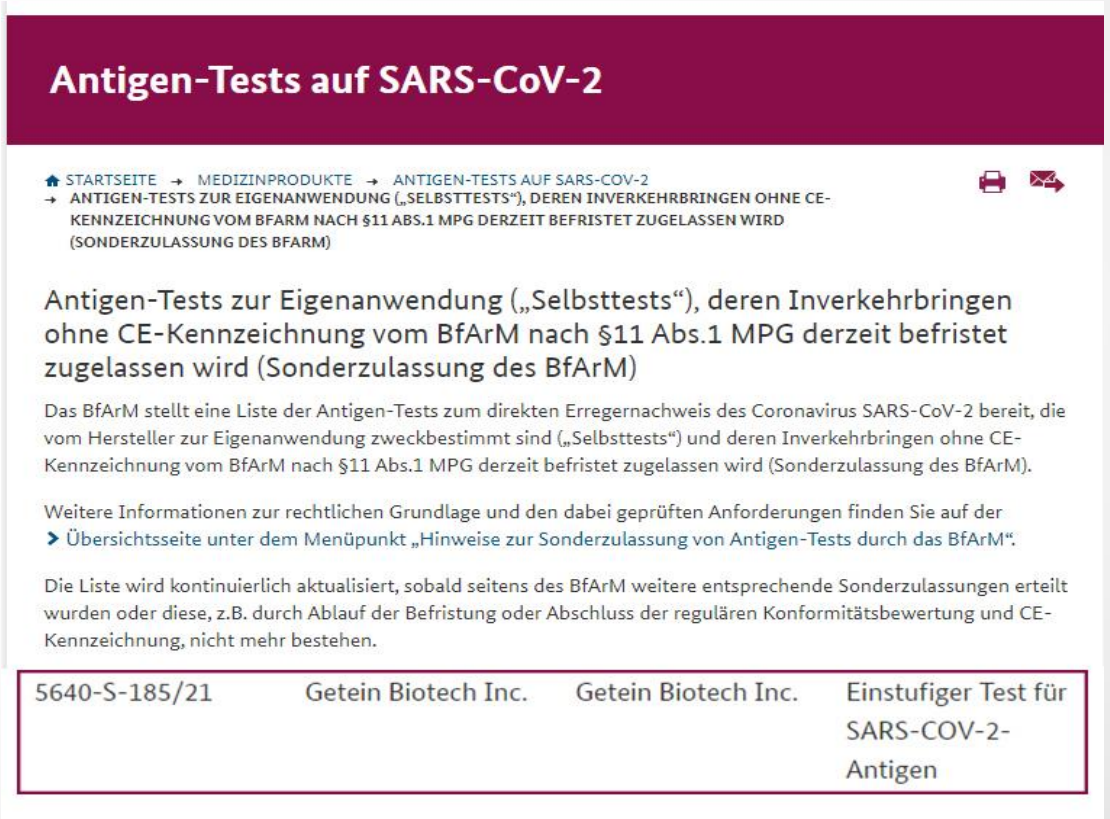
(place and date of issue)

(name and signature or equivalent marking of authorized person)

CE

基蛋生物新冠家用自测试剂被列入德国BfArM白名单

Getein One Step Test for SARS-CoV-2 Antigen Test Kit has been approved for self-testing by The Federal Institute for Drugs and Medical Devices of Germany (BfArM).



Antigen-Tests auf SARS-CoV-2

STARTSEITE → MEDIZINPRODUKTE → ANTIGEN-TESTS AUF SARS-COV-2
→ ANTIGEN-TESTS ZUR EIGENANWENDUNG („SELBSTTESTS"), DEREN INVERKEHRBRINGEN OHNE CE-KENNZEICHNUNG VOM BFARM NACH §11 ABS.1 MPG DERZEIT BEFRISTET ZUGELASSEN WIRD (SONDERZULASSUNG DES BFARM)

Antigen-Tests zur Eigenanwendung („Selbsttests"), deren Inverkehrbringen ohne CE-Kennzeichnung vom BfArM nach §11 Abs.1 MPG derzeit befristet zugelassen wird (Sonderzulassung des BfArM)

Das BfArM stellt eine Liste der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2 bereit, die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests") und deren Inverkehrbringen ohne CE-Kennzeichnung vom BfArM nach §11 Abs.1 MPG derzeit befristet zugelassen wird (Sonderzulassung des BfArM).

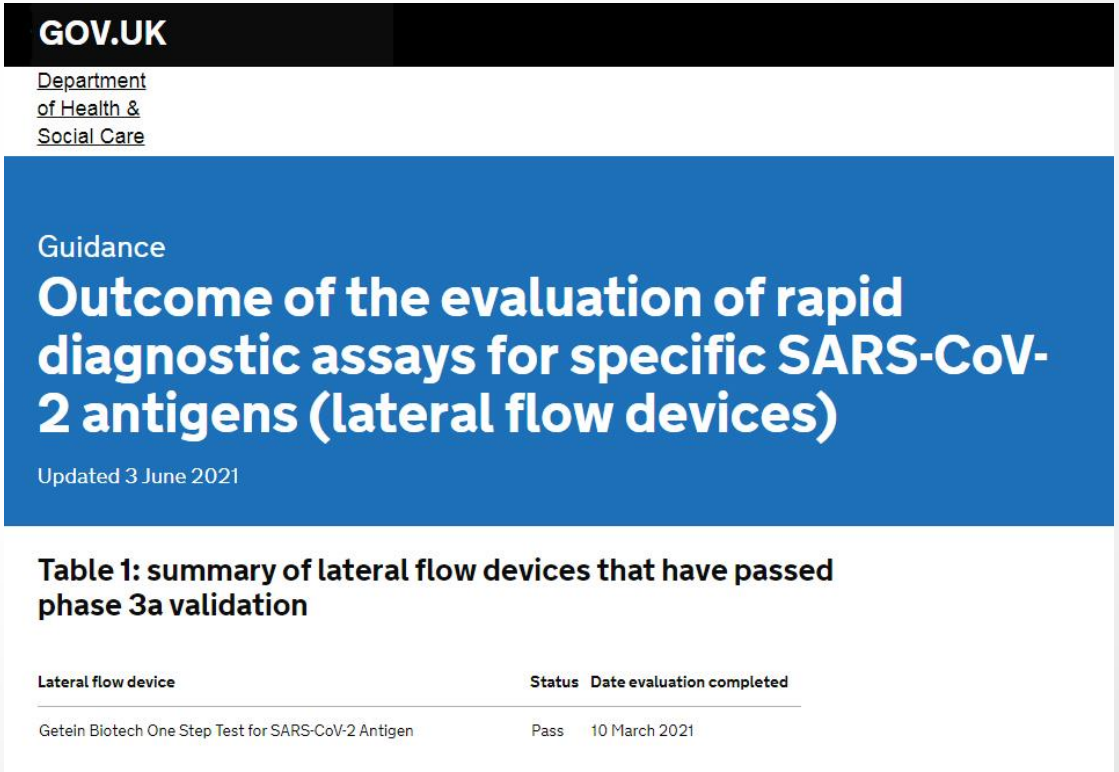
Weitere Informationen zur rechtlichen Grundlage und den dabei geprüften Anforderungen finden Sie auf der
> Übersichtsseite unter dem Menüpunkt „Hinweise zur Sonderzulassung von Antigen-Tests durch das BfArM".

Die Liste wird kontinuierlich aktualisiert, sobald seitens des BfArM weitere entsprechende Sonderzulassungen erteilt wurden oder diese, z.B. durch Ablauf der Befristung oder Abschluss der regulären Konformitätsbewertung und CE-Kennzeichnung, nicht mehr bestehen.

5640-S-185/21	Getein Biotech Inc.	Getein Biotech Inc.	Einstufiger Test für SARS-COV-2-Antigen

基蛋生物新冠家用自测试剂被列入英国MHRA自测名单

Getein One Step Test for SARS-CoV-2 Antigen Test Kit has been approved for self-testing by UK MHRA



GOV.UK

Department of Health & Social Care

Guidance

Outcome of the evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices)

Updated 3 June 2021

Table 1: summary of lateral flow devices that have passed phase 3a validation

Lateral flow device	Status	Date evaluation completed
Getein Biotech One Step Test for SARS-CoV-2 Antigen	Pass	10 March 2021

临床检测报告
Clinical Agreement Study

The clinical performance of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) was evaluated by testing a total of 480 nasal swab samples. It is compared to the results of RT-PCR assays. Overall study results were shown in the tables below.

Total		BGI's RT-PCR kit		
		positive	negative	Subtotal
Getein's kit	positive	165	4	169
	negative	5	306	311
	Subtotal	170	310	480

Positive percent agreement (Diagnostic sensitivity) = 165 / (165 + 5) ×100% = 97.06% (95% CI: 93.30%-98.74%)
Negative percent agreement (Diagnostic specificity) = 306 / (306 +4) × 100% = 98.71% (95% CI: 96.73%-99.50%)
Total percent agreement = (165 + 306) / 480 × 100% = 98.13% (95% CI: 96.48%-99.01%)

基蛋生物公司介绍
Introduction of Getein Biotech

公司简介 Brief Introduction

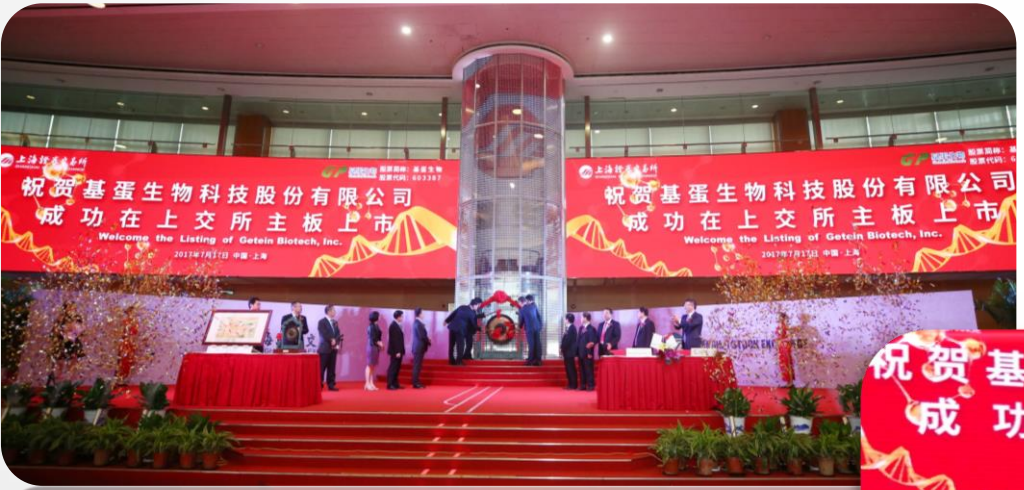
Getein Biotech Inc.

成立于2002年3月，是一家专业从事体外诊断试剂及配套仪器研发、生产和销售的国家火炬计划重点高新技术企业。目前，集团公司员工1700余人，从事高新技术研究开发的专业人员400余人。产品主要覆盖心血管疾病、肾损伤、传染病、肿瘤等重大疾病领域，广泛应用于各级医院、社区门诊、卫生院、实验室。

, established in 2002 and headquartered in Nanjing, is a fully integrated in vitro diagnostic (IVD) company that researches, manufactures, markets and distributes analytical medical devices and a broad range of innovative diagnostic test kits.

成功上市 Listed in SSE

2017年7月17日
17th July 2017



成功在上交所主板上市

股票代码：603387

Getein got listed in Shanghai Stock Exchange (SSE)

Stock Code: 603387

发展历程 Milestones

2002
Company Established

2003~2007
Research & Development Team Construction

2008~2009
Domestic Sales Largely Raised Up

2010
1st FIA8000 Launched

2011
ISO Certification
CE Mark

2012~2013
Overseas Sales Started

2014~2015
Product Lines Expanded

2016
Getein1600 Launched

2017~2019
Listed in SSE

2021

Chemiluminescence Clinical Chemistry launched

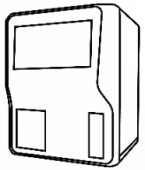
产品线 Product Lines

1

POCT

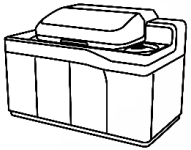
2

血液分析仪
Hematology



3

生化分析仪
Clinical Chemistry

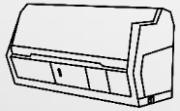


4

化学发光
Chemiluminescence

5

血凝
Coagulation



6

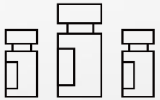
分子诊断
Molecular Diagnostics

7

尿液分析
Urinalysis

8

质控品
Controls



9

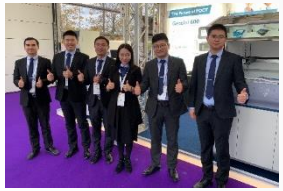
新冠病毒COVID-19检测方案
COVID-19 Test Solutions

线下展会 Marketing Activities

CMEF China International Medical Equipment Fair

MEDLAB WEST AFRICA

AACC



AFRICA HEALTH

Feira Fórum Hospitalar

ARAB HEALTH

FIME

MEDICA

追求卓越，传递健康
Pursuing Excellence, Passing on Health

Taking people's wellbeing as the motivation, we are dedicated to contributing to people's health and helping people from different countries live a happy and well life.

谢谢观阅
Thanks for Your Attention