

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

For self-test





Product Pictures

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

For Self-test

Contains: 1) SARS-CoV-2 antigen test card: 5 tests

- 2) Sample extraction solution: 0.4mL×5 tubes
- 3) Disposable sampling swab(C € oter): 5 pcs
- 4) Disposable pipette: 5 pcs
- 5) Biohazard sample bag: 5 pcs
- 6) User manual: 1 r















- SARS-CoV-2 Antigen Test Card

—Biohazard Sample Bag

Disposable Sampling Swab



Specifications

Info. of the Test Kit and Export Packing Cartons

Product Name	Specifications	Size (cm)	Weight/Kit (g)	Kit Quantity/Carton	Size of Carton (cm)	Weight per Carton (kg)
One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	1 Test/Kit	7*1.8*13 cm	25.5 g	300 Kits/Carton	49.5*40.5*30 cm	8.6 kg/Carton
	5 Tests/Kit	7*5.3*13 cm	76.6 g	120 Kits/Carton	55.5*41*30 cm	10.44 kg/Carton

Export Packing Cartons



Packing carton for 5 T/kit Size: 55.5*41*30 cm



Packing carton for 1 T/kit Size: 49.5*40.5*30 cm



Brochure

STOCK CODE 603387



One Step Test for SARS-CoV-2 Antigen

(Colloidal Gold)

For self-test

CE Marked

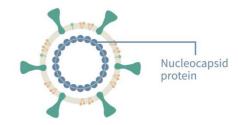
Rapid, Convenient, Easy and Reliable Detection of COVID-19



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

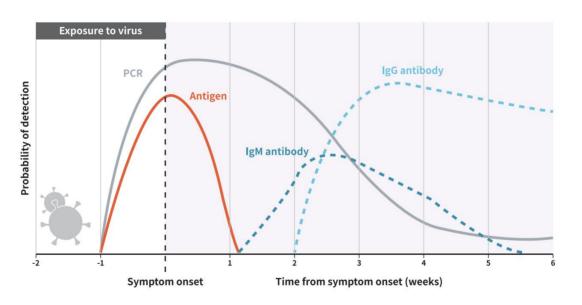


Disposable sampling swab



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)



Read test results visually. Do not require test equipment.



Early detection of SARS-CoV-2 infection



Rapid test.
Test result available in 10-15 min.



Simple operation, easy to learn and use



Room temperature storage (4-30°C)

When to Use the Test Kit?

Use this test:

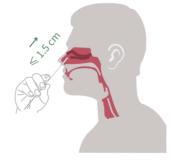
- ☑ If you have symptoms similar to COVID-19, such as: E.g. headache, fever, cough, sore throat, loss of sense of smell or taste, shortness of breath, muscle pain.
- **⊘** If you are concerned about whether you are infected with COVID-19.
- **⊘** Use of the test by persons under 18 years of age only under the supervision of an adult.

Operation Video



Test Procedure





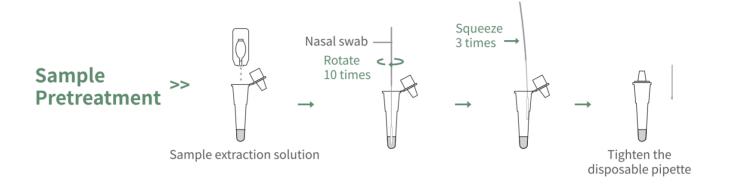
Insert the collection tip of swab into one nostril.

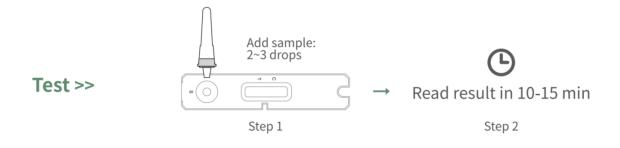


Rotate ≥ 4 times (15 s in total)

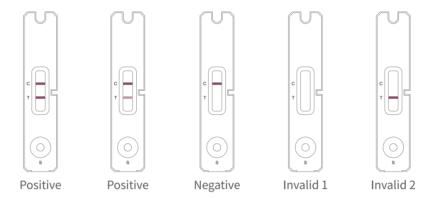


Repeat with the same swab.





Test Results



Specifications

Product Name	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)		
Test Item	SARS-CoV-2 Antigen		
Package	1 T/kit, 5 T/kit, 7 T/kit, 25 T/kit		
Product Code	CG20615/ CG206155/ CG206157/ CG2061525		
Test Time	10-15 min		
Storage Condition	4-30°C		
Shelf Life	24 months		
Recommended Test Temperature	23-25°C		

Application Scenarios



















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CMC Medical Devices & Drugs S.L.

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Tel: +34951214054















User Manual



One Step Test for C € 1434 SARS-CoV-2 Antigen (Colloidal Gold)

User Manual for self-test



















Timer (Not included)

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 used for individuals suspected of COVID-19 within the first seven days of the onset of symptoms, such as headache, fever, cough, sore throat, loss of the sense of smell or taste, shortness of breath, muscle pain. Meanwhile the test can also be applied for individuals without symptoms. Results are for the identification of SARS-CoV-2 antigen. Positive results indicate the presence of SARS-CoV-2 antigens, but individual history and other diagnostic information is necessary for determine infection status. Negative results do not rule out SARS-CoV-2 infection. Negative results for individuals with symptoms similar to COVID-19 infection for more than seven days should be treated as negative possibly. If necessary, it should be confirmed by molecular assay. One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended to be used to help the diagnosis of SARS-CoV-2 infection. This test is used for self-test.

PREPARING THE TEST



Check integrity of the out package. components and the expiration date.



Read the user manual before starting the test. Check introduction video for more help

3.





Result wantow

Open the pouch. Check the result window and sample well (s).

SPECIMEN COLLECTION





Self collection (≥18 years)

Collection and test by caregiver (<18 years, sick, elderly. disabled persons)

Note: Please follow your local guideline for specimen collection.

TEST PROCEDURE



Pour sample extraction solution into the disposable pipette and place it into the package.



Squeeze the swab tip along the inner wall of the disposable pipette 3 times.



Open the swab packag. Gently insert the tip of the swab into one nostril. Do not insert the swab more than 1.5 cm into your nose.



Tighten the disposable pipette, gently squeeze the disposable pipette and add 2~3 drops of solution into the sample well (s).

3.



Rotate the swab around the inside wall of your nostril at least 4 times. Repeat the same process with the same swab in the other nostril.



10-15 min

Read the result visually in 10~15 min, don't read results after 20 min.



Insert the swab after sampling to the disposable pipette and rotate the swab 10 times in the solution.



Put all of the used test kit contents in the biohazard sample bag provided and put this in household waste. If necessary, discarded all used tests according to local regulations. Wash your hands thoroughly after disposal.

TEST RESULTS



Positive (+):

Both the control line (C) and test line (T) appear indicates the presence of SARS-CoV-2 antigen. Any faint line in the test line (T) should be considered positive.

Note: Positive results indicate the very likely infected COVID-19. Contact your doctor or the local health department immediately. Follow the local guidelines for self-isolation and confirmed by a molecular testing method.



Negative (-):

Only the control line (C) and no test line (T) appear indicates no SARS-CoV-2 antigen was detected.

Note: Negative results indicate the unlikely infected COVID-19. Continue to follow all applicable rules and protective measures when contacting with others. There may be an infection even if the test is negative. If it is suspected, repeat the test after 1 - 2 days or confirmed by a molecular testing method.



Invalid

Control area (C)fails to appear, the test result is invalid. Not enough sample volume or incorrect operation are the likely reasons for an invalid result. Read the instructions again and test with a new test. If the same situation reappears. please stop using this batch of products and contact your doctor or a COVID-19 test center.

STORAGE AND STABILITY

Store the test kit at 4-30°C with a valid period of 24 months. Use the test card within 1 hour once the foil pouch is opened.

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 IT The color intensity of each test line increases in proportion to the amount of SARS-CoV-2 antigen in sample.

PRECAUTIONS

- 1. Always keep out of the reach of children. Small parts of the kit can be a
- 2. Sample extraction solution is a phosphate buffer contained low concentration of sodium chloride. Tween, hexadecyl trimethyl ammonium bromide and sodium azide. If extraction solution splashes your body or into eyes. please wash with water.

LIMITATIONS

- 1. False-negative result may occur if the level of antigen in sample is below the detection limit of the test or the sample was collected
- 2. Clinical diagnosis and treatment cannot be made without consulting with the physician
- 3. A negative result, from an individual have symptoms similar to COVID-19 beyond seven days should be treated as negative possibly. If necessary, confirmed with the molecular assay.
- 4. The product One Step Test For SARS-CoV-2 Antigen (Colloidal Gold) showed no drop off in sensitivity when compared with the wild type with respect to the following variants-VOC1 UK, Alpha, VOC2 South Africa, Beta, VOC3 Brazil Gamma, VOI1 America lota and VOI2 India Kappa. We will keep evaluating the impact of new variants.

PERFORMANCE CHARACTERISTICS

1 Limit of Detection (LoD)

The LoD for nasal swab was established using heat-inactivated SARS-CoV-2 isolate strain. The strain was spiked with negative human hasal. swab into a series of concentrations. 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. /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	positive	165	4	169	
kit -	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 was 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 105 PFU/mL
Human coronavirus OC43	1 x 105 PFU/mL
Human coronavirus NL63	9.87 x 103 PFU/mL
MERS coronavirus	7930 PFU/mL
Adenovirus (e.g. C1 Ad. 71)	1 x 105 PFU/mL
Human Metapneumovirus (hMPV)	1 x 105 PFU/mL
Parainfluenza virus Type 1	1 x 105 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 104 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 ^e CFU/mL
Streptococcus pyogenes	1 x 10 ^e CFU/mL
Candida albicans	1 x 10 ⁶ CFU/mL
Pooled human nasal wash	14%v/v
Bordetella pertussis	1 x 10 ^o CFU/mL
Mycoplasma pneumoniae	1 x 10 ^o CFU/mL
Chlamydia pneumoniae	1 x 10° CFU/mL
Legionella pneumophila	1 x 10 ⁶ CFU/mL
Mycobacterium tuberculosis	1 x 10 ⁸ CFU/mL
Pneumocystis jirovecii	1 x 10 ^s CFU/mL
Pseudomonas Aeruginosa	1 x 10 ^s CFU/mL
Staphylococcus Epidermidis	1 x 10 ^s 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). 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				

4.Precision

For repeatability study, the agreement percent of both negative samples and positive samples are 100%. For reproducibility study, the agreement percent of both negative samples and positive samples are 100%.

DESCRIPTION OF SYMBOLS USED

Key to symbols used						
***	Manufacturer		Use-by date			
(2)	Do not re-use	~··	Date of manufacture			
\square i	Consult instructions for use	LOT	Batch code			
4C 10C	Temperature limit	IVD	In vitro diagnostic medical device			
Σ	Contains sufficient for <n> tests</n>	EC REP	Authorized representative in the European Community			
*	Keep away from sunlight	8	Do not use if package is damaged			
REF	Catalogue number	*	Keep away from rain			
ħ	For self-testing	C€ ₁₄₃₄	CE mark			
₩	Biological risks					



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

> Version: WCG93-DXF-S-03 Last Edition:12/07/2021

Specification (N)	REF
1 T/kit	CG20615
2 T/kit	CG206152
3 T/kit	CG206153
5 T/kit	CG206155
6 T/kit	CG206156
7 T/kit	CG206157
8 T/kit	CG206158
9 T/kit	CG206159
10 T/kit	CG2061510
12 T/kit	CG2061512
15 T/kit	CG2061515
20 T/kit	CG2061520
25 T/kit	CG2061525



Certificates and Clinical Evaluation



Getein COVID-19 Test Kits on the Export Whitelist of China

序号 No.	生产企业 Manufacturer	统一社会信用代码 Certificate for Uniform Social Credit	国外注册认证情况 Certificate	省份 Province of China	产品型号 Product Name
42	基蛋生物科技股份有限公司 Getein Biotech, Inc.	913201007360621166	CE	江苏 Jiangsu	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) SARS-CoV-2 Neutralizing Antibody Fast Test KIt (Immunofluorescence Assay) One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) (Saliva)
623	基蛋生物科技股份有限公司 Getein Biotech,Inc.	913201007360621166	Austria BASG Listing	江苏 Jiangsu	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) (Nasal) Selftest





EC Certificate No. 1434-IVDD-447/2021

EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies that manufactured by:

GETEIN Biotech, Inc.

Nanjing, ul. Bofu Road, Luhe District 9, China

in vitro diagnostic medical devices for self-testing

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

Ref. codes: CG20615, CG206152, CG206153, CG206155, CG206156, CG206157, CG206158, CG206159, CG2061510, CG2061512, CG2061515, CG2061520, CG2061525

in terms of design documentation, comply with requirements of Annex III (Section 6) to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 30.07.2021



Issued under the Contract No. MD-66/2021 Application No: 142/2021 Certificate bears the qualified signature. Warsaw, 30.07.2021 Module A1



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

>>

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.

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Total percent agreement = $(165 + 306) / 480 \times 100\% = 98.13\%$ (95% CI: 96.48%-99.01%)



Introduction of Getein Biotech



Getein Biotech Inc.

Getein Biotech Inc. (stock code: 603387), 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.



Getein got listed in Shanghai Stock Exchange (SSE)



Chemiluminescence Clinical Chemistry launched



Overseas Sales Started

2012~2013





2021

2017~2019

Listed in SSE



2003~2007

Research & Development Team Construction







2008~2009

Domestic Sales

Largely Raised Up

2010



1st FIA8000 Launched

Product Lines Expanded 2011









2014~2015













POCT



2

Hematology





Clinical Chemistry



4

Chemiluminescence



5

Coagulation



6

Molecular Diagnostics



7

Urinalysis



8

Controls



9

COVID-19 Test Solutions







Nucleic Acid Test



Antigen Test



Neutralizing Antibody Test



IgM/IgG Antibody Test

Comprehensive Testing Solution of COVID-19 =

Antigen Test of SARS-CoV-2

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



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



For professional use

 SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay)



Neutralizing Antibody Test of SARS-CoV-2

 One Step Test for SARS-CoV-2 Total Antibody/ Neutralizing Antibody (Colloidal Gold)



 SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay)



Antibody Test of SARS-CoV-2

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



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



Distinction Test of FluA/FluB/SARS-CoV-2 Antigen

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





SARS-CoV-2 Nucleic Acid Detection One-Station Solution



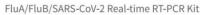
Novel Coronavirus (2019-nCoV) Real-time RT-PCR Kit



SARS-CoV-2/VOC-202012/01 Real-time RT-PCR Kit









Disposable Virus Sampling Tube



Nucleic Acid Extraction Kit

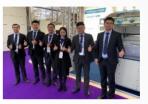


























Pursuing Excellence, Passing on Health

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.





Thanks for Your Attention

