STOCK CODE 603387

Getein Biotech, Inc.

One Step Test for SARS-CoV-2 Antigen

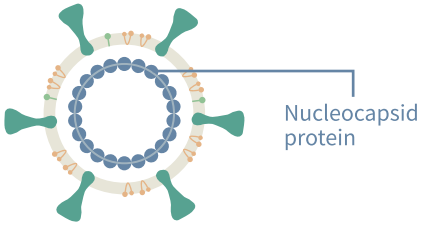
(Colloidal Gold) • For self-test

CE Marked

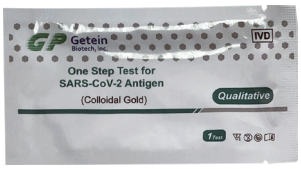
Rapid, Convenient, Easy and Reliable Detection of COVID-19

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



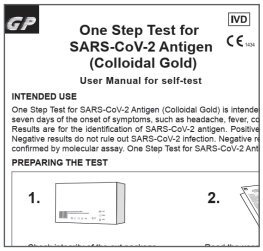
SARS-CoV-2 antigen test card

Sample extraction solution

Disposable pipette

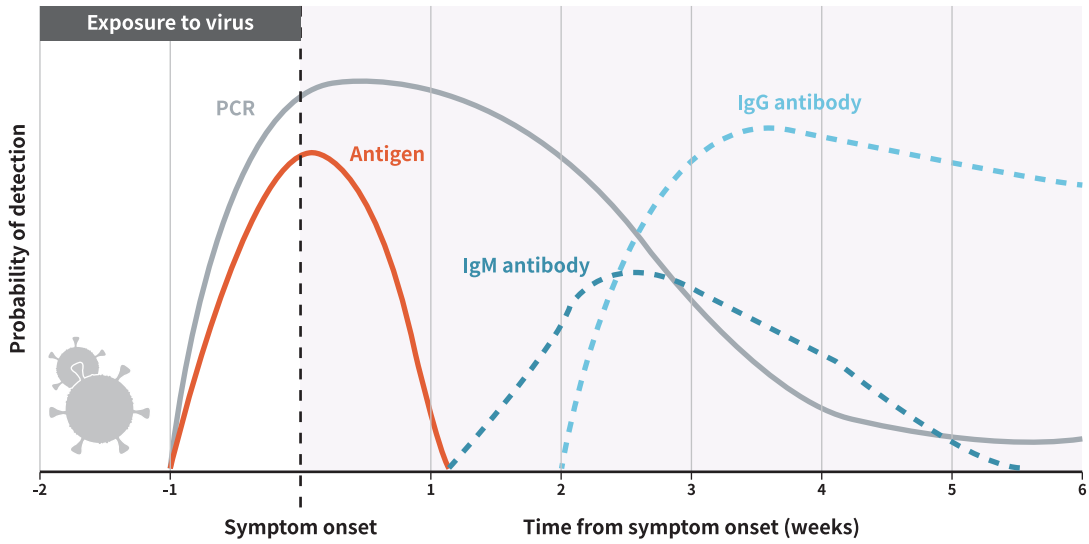
Biohazard sample bag

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:

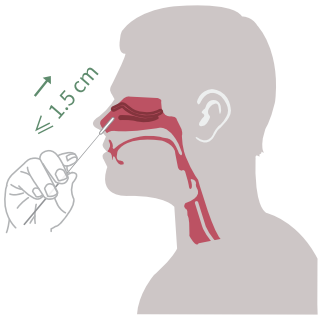
- If you want to test yourself.
- If you have symptoms similar to COVID-19, such as: E.g. headache, fever, cough, sore throat, loss of sense of smell or taste, shortness of breath, muscle pain.
- If you are concerned about whether you are infected with COVID-19.
- Use of the test by persons under 18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

Operation Video

Scan the QR code to get operation video

Test Procedure

Nasal Swab Sampling >>



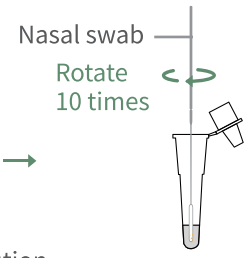
Insert the collection tip of swab into one nostril.

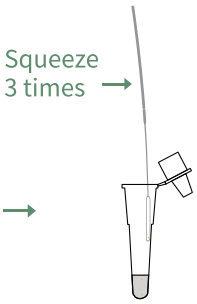
Rotate ⩾ 4 times (15 s in total)

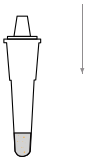
Repeat with the same swab.

Sample Pretreatment >>

Sample extraction solution

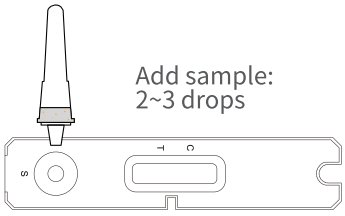






Tighten the disposable pipette

Test >>

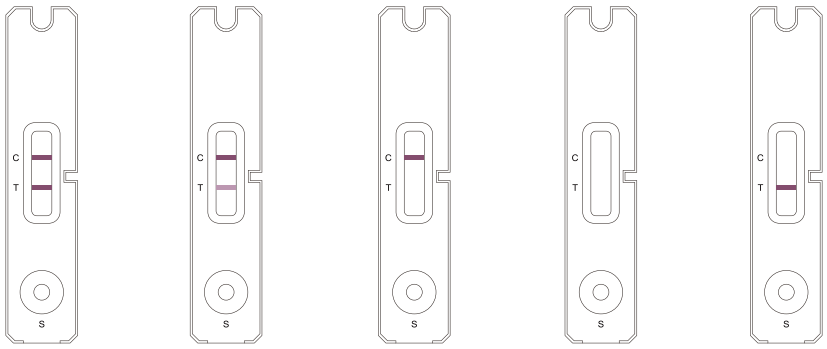


Step 1

Read result in 10-15 min

Step 2

Test Results



Positive | Positive | Negative | Invalid 1 | Invalid 2

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

Home | School | Work Place | Dormitory

Nursing Home | Cruise ship | Airport | Theater

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Web: 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

ISO13485 CE 1434 IVD

CERTIFICATE

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

CE 1434

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

Vice-President

Declaration of Conformity

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

Ref. No.:20210816-A01

Manufacturer (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China
Authorized Representative (Name, Address)	**CMC Medical Devices & Drugs S.L.** Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

	Product Name	**GMDN Code**
Medical device	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	65454

Catalogue number	CG20615, CG206152, CG206153, CG206155, CG206156, CG206157, CG206158, CG206159, CG2061510, CG2061512, CG2061515, CG2061520, CG2061525
Classification	Self-testing (according to Article 1 (d) of 98/79/EC)
Conformity assessment route	Annex III section 6 of the 98/79/EC

Applicable coordination standards

EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-4-2011
EN ISO 23640:2013	EN ISO 13485:2016	EN ISO 780: 2015
EN 62366:2008	EN 13641:2002	EN 980:2008
EN 13975:2003	EN 13532:2002	

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 I. 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, the EC certificate has issued by Polish Centre for Testing and Certification. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

Nanjing, 16th Aug, 2021

(place and date of issue)

Enben Su

(name and signature or equivalent marking of authorized person)

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

User Manual for self-test

IVD

CE 1434

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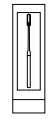
SARS-CoV-2 antigen test card
N test


Sample extraction solution
N tube


Disposable pipette
N pc

Biohazard sample bag
N pc


User manual
1 pc/kit


Disposable sampling swab
N pc(sterile product, CE0197)


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

1.

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

2.

INSTRUCTION VIDEO

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

3.

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

SPECIMEN COLLECTION

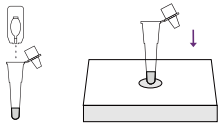
Self collection
(≥18 years)

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

Note: Please follow your local guideline for specimen collection.

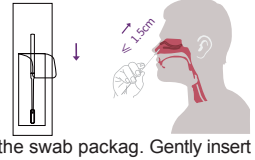
TEST PROCEDURE

1.



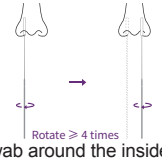
Pour sample extraction solution into the disposable pipette and place it into the package.

2.



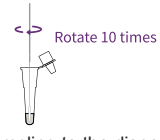
Open the swab packag. Gently insert the tip of the swab into one nostril. Do not insert the swab more than 1.5 cm into your nose.

3.



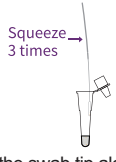
Rotate the swab around the inside wall of your nostril at least 4 times. Repeat the same process with the same swab in the other nostril.

4.



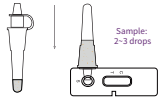
Insert the swab after sampling to the disposable pipette and rotate the swab 10 times in the solution.

5.



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

6.



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

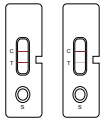
7.

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

8.

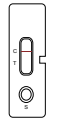
Put all of the used test kit contents in the biohazard sample bag provided and put this in household waste. If necessary, discarded all used tests according to local regulations. Wash your hands thoroughly after disposal.

TEST RESULTS



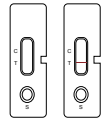
Positive

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

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

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 card at 4-30℃ 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 4-30℃ with a valid period of 24 months.

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.

PRECAUTIONS

1. Always keep out of the reach of children. Small parts of the kit can be a choking hazard.
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 incorrectly.
2. The test kit cannot differentiate between SARS-CoV and SARS-CoV-2.
3. Clinical diagnosis and treatment cannot be made without consulting with the physician.
4. 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.
5. 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 Iota 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 nasal 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 $TCID_{50}$/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 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 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
Pooled human nasal wash	14%v/v
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). 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
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
4℃ 30℃	Temperature limit	IVD	In vitro diagnostic medical device
Σ	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
	For self-testing	CE 1434	CE mark
	Biological risks		

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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