

Getein

Einstufiger Sars-COV-2

ANTIGEN LAIENTEST

Produktbezeichnung

Getein Einstufiger Sars-COV-2
ANTIGEN LAIENTEST

Art.-Nr.

GTLN01/GTLN05

Einheit

1 Test /Box; 300 Tests/ Karton

5 Test /Box; 600 Tests/ Karton

Lagertemperatur

4-30 °C

Probenart

Nasenabstrich(1,5cm tief)

Hersteller

Getein Biotech, Inc.

Abmessungen Karton

1er-VE: 49,5cm x 40,5cm x 30cm; 8,6kg

5er-VE: 55,5cm x 41cm x 30cm; 10,4 kg



VORTEILE

Antigen Laientest zur Selbstanwendung

Hochpräzise Ergebnisse nach
15 Minuten

Einfache Handhabung ohne
zusätzliches Analysesystem

Vorderer Nasenabstrich
(bis 1,5 cm tief in die Nase)

Aufbewahrung bei
Raumtemperatur

Sensitivität

97,06%

Spezi ität

98,71%

Genauigkeit

98,13%

Lieferumfang

Testkassette

Probenextraktionspuffer

Einweg-Virusprobenabstrich

Müllbeutel für kontaminierten Abfall

Gebrauchsanweisung

Zertifizierung

CE 1434 seit 30.07.2021

Paul-Ehrlich-Institut evaluiert

ED List Device # 1820 HSC

Common List



HansaGT Medical GmbH
Tochtergesellschaft der Deutsche
HansaGT GmbH

Hardenstr. 51 • 20539 Hamburg
USt-ID Nr. DE 342278289
Steuer-Nr.: 46/714/04969
Handelsregister HRB 167631

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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



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 N° 18, CP 29006, Málaga, Spain

Medical device **Product Name** **GMDN Code**
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)


(name and signature or equivalent marking of authorized person)

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

User Manual for self-testing



CONTENTS



SARS-CoV-2 antigen test card N test



Extraction tube with sample extraction solution and tip N pc



Biohazard sample bag N pc



User manual 1 pc/kit



Sterile swab N pc



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-testing.

PREPARING THE TEST

1.



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

2.



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



Operation Video

3.



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

SPECIMEN COLLECTION



Self collection (≥18 years)

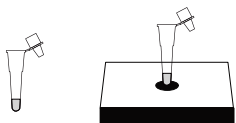


Collection and test by caregiver (<18 years, sick, elderly, disabled persons)

Note: Please follow your local guideline for specimen collection.

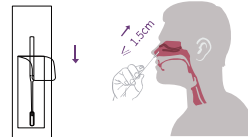
TEST PROCEDURE

1.



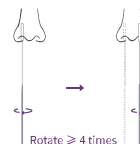
Remove the lid from the top of the extraction tube with sample extraction solution and place it into the package.

2.



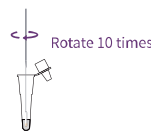
Open the swab packag. Gently insert the tip of the swab into one nostril. Do not insert the swab more than 1.5 cm into your nose.

3.



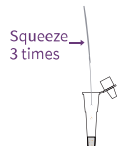
Rotate the swab around the inside wall of your nostril at least 4 times. Repeat the same process with the same swab in the other nostril.

4.



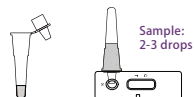
Insert the swab after sampling to the extraction tube and rotate the swab 10 times in the solution.

5.



Squeeze the swab tip along the inner wall of the extraction tube 3 times.

6.



Push the tip into the extraction tube and ensure it fits tightly. Gently squeeze the extraction tube and add 2-3 drops of solution into the sample well (S).

7.



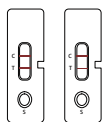
Read the result visually in 10-15 min, don't read results after 20 min.

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.

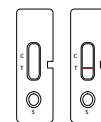


Negative

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 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 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. 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 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 TCID₅₀/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) = $165 / (165 + 5) \times 100\% = 97.06\%$ (95% CI: 93.30%-98.74%)

Negative percent agreement (Diagnostic specificity) = $306 / (306 + 4) \times 100\% = 98.71\%$ (95% CI: 96.73%-99.50%)

Total percent agreement = $(165 + 306) / 480 \times 100\% = 98.13\%$ (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
Nasal 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 Phenol Spray	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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community
	Keep away from sunlight		Do not use if package is damaged
	Catalogue number		Keep dry
	For self-testing		CE mark
	Biological risks		

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Version: WCG93-DXF-S4-02
Last Edition: 17/08/2021

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