COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) -self testing

Introduction Materials

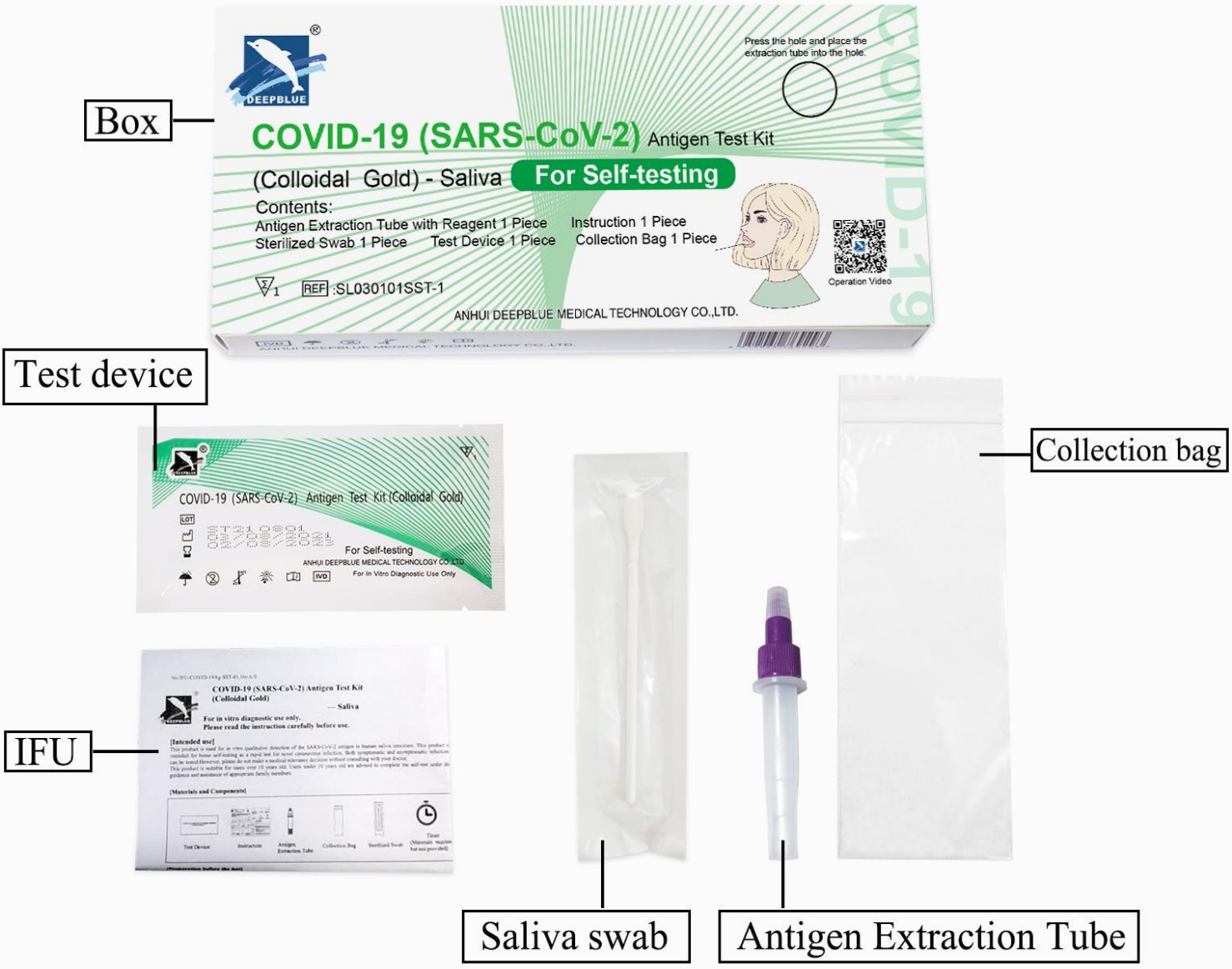
Anhui Deepblue Medical Technology Co.,Ltd.
Website:www.dbluemedical.com
Address:4th Floor D-1# Zone, Pearl Industrial Park 106 Innovation Avenue,High-Tech Development Zone 230088 Hefei, Anhui, China


DEEPBLUE
Press the hole and place the extraction tube into the hole.
COVID-19 (SARS-CoV-2) Antigen Test Kit
(Colloidal Gold) - Saliva
For Self-testing
Contents:
Antigen Extraction Tube with Reagent 1 Piece
Instruction 1 Piece
Sterilized Swab 1 Piece
Test Device 1 Piece
Collection Bag 1 Piece
Σ1 REF :SL030101SST-1
Operation Video
ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.


DEEPBLUE
Press the hole and place the extraction tube into the hole.
COVID-19 (SARS-CoV-2) Antigen Test Kit
(Colloidal Gold) - Saliva
For Self-testing
Contents:
Antigen Extraction Tube with Reagent 5 Pieces
Instruction 1 Piece
Sterilized Swab 5 Pieces
Test Device 5 Pieces
Collection Bag 5 Pieces
Σ5 REF :SL030101SST-5
Operation Video
ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

1pcs / box,10 boxes / medium box,45 medium box/ carton--450pcs/carton box
size：145*65*20mm
medium boxsize：205*150*68mm,
carton size:63.5*47.5*36.5cm, 15kg

5pcs / box，240boxes /carton --1200pcs /carton
box size：190*65*40mm
carton size:60*43*55cm,21kg



Your kit contains the following materials

- Box
- IFU
- Saliva swab
- Test device
- Collection bag
- Antigen Extraction Tube

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 003706 0001 Rev. 01

Holder of Certificate: **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
4th Floor, D-1# Zone
Pearl Industrial Park
106 Innovation Avenue, High-Tech Development Zone
230088 Hefei, Anhui
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents by Colloidal Gold and Enzyme Chemical Reaction Method, Medical Ultrasonic Couplant, Acetowhite Solution, Epithelial Tissue Staining Solution, Rapid Test for Vaginitis(Polyamines) and Cell Preservation Solution**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 003706 0001 Rev. 01

Report No.: SH21130301

Valid from: 2021-06-22
Valid until: 2024-06-21

Date, 2021-06-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 003706 0001 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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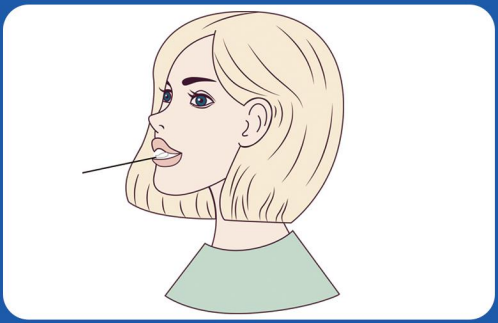
TÜV®

COVID-19 (SARS-CoV-2) Antigen test kit

(Self-Testing)



Specification	1 pcs/box 5 pcs/box 25 pcs/box
Specimen	Human Saliva
Storage	4~30℃

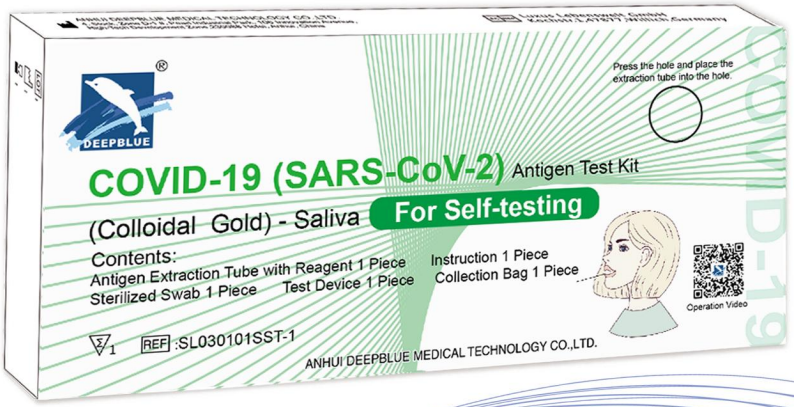
PERFORMANCE

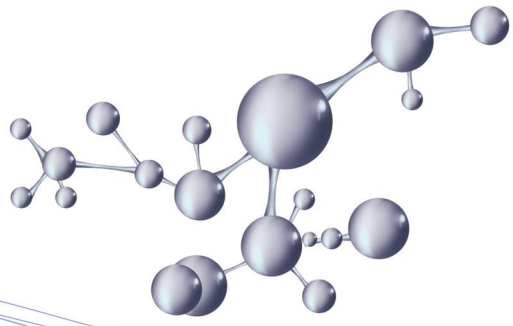
SENSITIVITY: 97.1%(95%CI: 90.8%-98.2%)

SPECIFICITY: 99.8%(95%CI: 94.4%-99.9%)

PRODUCT FEATURES

- Room temperature storage.
- No need instrument, get results within 15 minutes.
- Identify acute or early infection.
- No reduction in sensitivity test against the UK, South African, Brazilian and Delta variant.

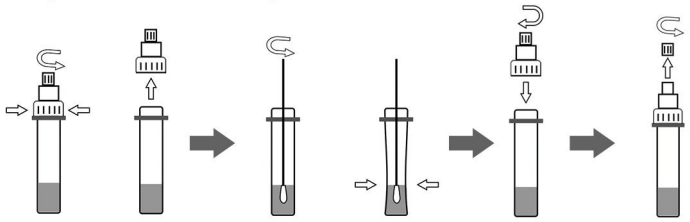




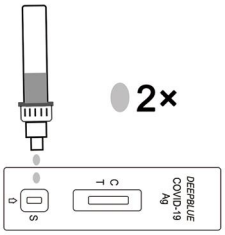
TEST PROCEDURE

1.Specimen Collection

2.Specimen Preparation

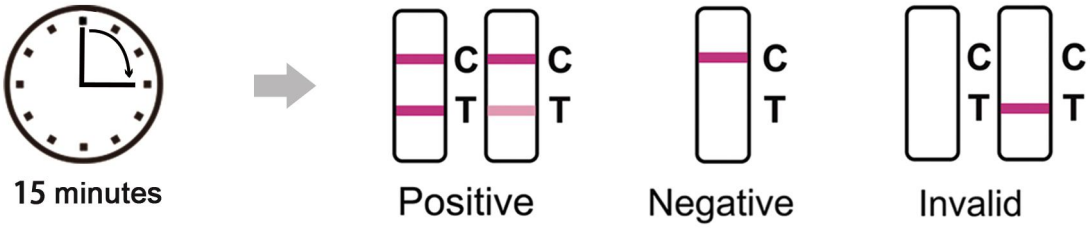


3.Testing



Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer. Interpret the results at 15 minutes, and the results after 30 minutes are no longer valid.

3.Interpretation of test results

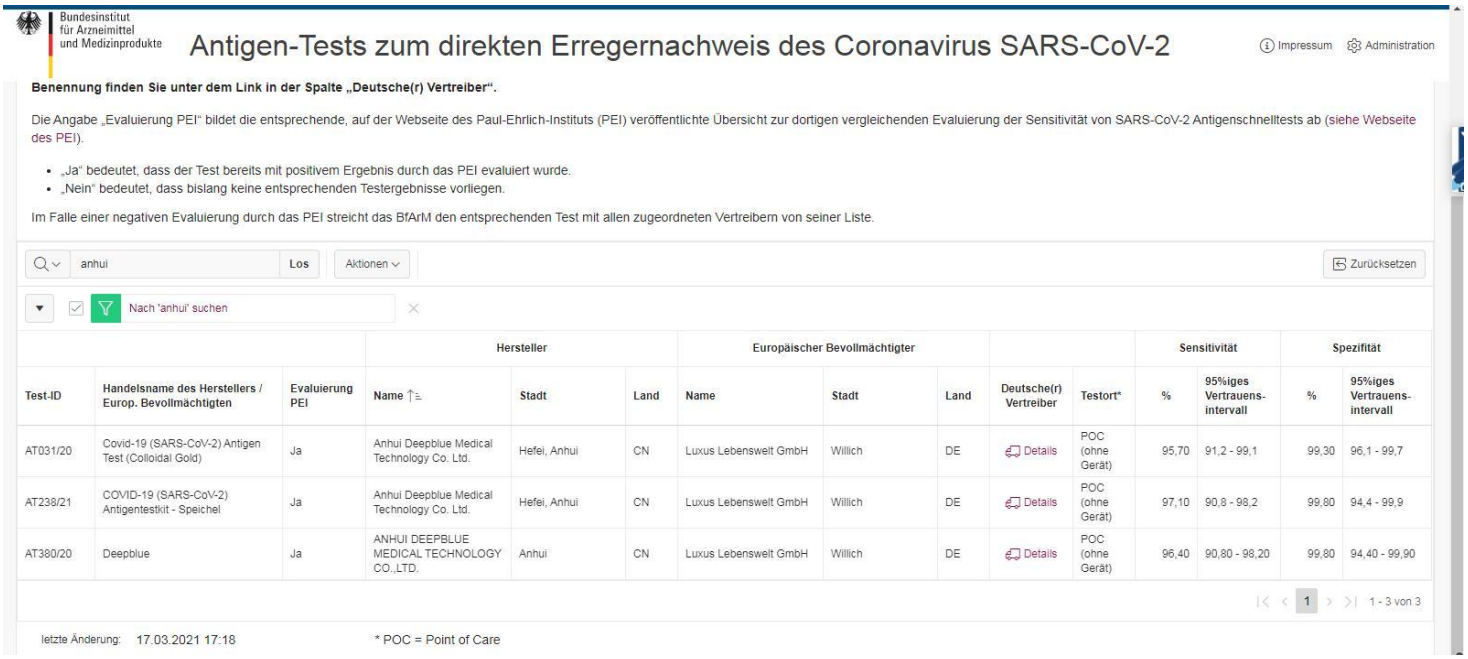


Scan the following QR code to watch the demonstration video on YouTube.

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

【Address】4th, Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, Hefei 230088, Anhui, China

【Website】www.dbluemedical.com 【Contact】0551-65326797



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum Administration

Benennung finden Sie unter dem Link in der Spalte „Deutsche(r) Vertreiber".

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden Test mit allen zugeordneten Vertreibern von seiner Liste.

anhui | Los | Aktionen | Zurücksetzen

Nach 'anhui' suchen

			Hersteller			Europäischer Bevollmächtigter					Sensitivität		Spezifität	
Test-ID	Handelsname des Herstellers / Europ. Bevollmächtigten	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Deutsche(r) Vertreiber	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauens-intervall
AT031/20	Covid-19 (SARS-CoV-2) Antigen Test (Colloidal Gold)	Ja	Anhui Deepblue Medical Technology Co. Ltd.	Hefei, Anhui	CN	Luxus Lebenswelt GmbH	Willich	DE	Details	POC (ohne Gerät)	95,70	91,2 - 99,1	99,30	96,1 - 99,7
AT238/21	COVID-19 (SARS-CoV-2) Antigentestkit - Speichel	Ja	Anhui Deepblue Medical Technology Co. Ltd.	Hefei, Anhui	CN	Luxus Lebenswelt GmbH	Willich	DE	Details	POC (ohne Gerät)	97,10	90,8 - 98,2	99,80	94,4 - 99,9
AT380/20	Deepblue	Ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	Anhui	CN	Luxus Lebenswelt GmbH	Willich	DE	Details	POC (ohne Gerät)	96,40	90,80 - 98,20	99,80	94,40 - 99,90

1 - 3 von 3

letzte Änderung: 17.03.2021 17:18

* POC = Point of Care

BfArM List with PEI Validation

中国医药保健品进出口商会

服 务 产 业 链 | 助 力 国 际 化

English 登陆 | 注册

请输入关键词进行搜索

开具不可抗力相关事实性证明 取得国外认证和注册企业查询

首页 关于商会 新闻中心 行业服务 权威发布 商会会刊 企业风采 会员之家 加入商会

取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

安徽深蓝医疗科技股份有限公司 检索

企业名称（中文）	企业名称（英文）	产品类别	产品名称/型号	统一社会信用代码	国外注册认证情况
安徽深蓝医疗科技股份有限公司	Anhui Deepblue Medical Technology Co., Ltd.	新型冠状病毒检测试剂	COVID-19(SARS-CoV-2) Antibody Test Kit(Colloidal Gold) COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) Influenza A+B & COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) COVID-19 (SARS-CoV-2) Antibody & Antigen Combo Test Kit (Colloidal Gold)	913401005501903714	欧盟CE

友情链接

DeepBlue White List

COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)

— Saliva

For in vitro diagnostic use only.
Please read the instruction carefully before use.

Operational Use Video

[Intended use]

This product is used for in vitro qualitative detection of the SARS-CoV-2 antigen in human saliva specimen. This product is intended for home self-testing as a rapid test for novel coronavirus infection. Both symptomatic and asymptomatic infections can be tested.However, please do not make a medical relevance decision without consulting with your doctor.
This product is suitable for users over 10 years old. Users under 10 years old are advised to complete the self-test under the guidance and assistance of appropriate family members.

[Materials and Components]


Test Device


Instruction


Antigen Extraction Tube


Collection Bag


Sterilized Swab


Timer (Materials required but not provided)

[Preparation before the test]


Clean your hands, make sure they are dry before starting the test.


Read the instructions carefully

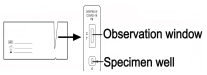

Check all parts of the test kit to make sure that all parts are complete and not damaged.


Check the Expiration Date printed on the foil pouch of the cassette.

[Test Procedure]

Allow test device extraction reagent and specimens to equilibrate to room temperature (15 ~ 30 ℃） **prior to testing.**
Please keep the temperature at 15 ~ 30 ℃ and the humidity at 20%-80% during the whole test.

1.



Open the package and take out the test device.Know the observation window and specimen well(S).It should be used within one hour.

2.

Unscrew the cap of the extraction tube counterclockwise

3.

Press the pre-drilled circle, make a hole in the outer box, and then insert the bottom of the antigen extraction tube into the hole.

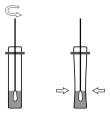
4.

Remove the sterilized swab from the packaging.

5.

Insert the soft tip of sterilized swab into the mouth, actively swab inside of the mouth and tongue to collect saliva for approximately 30-60s until the soft tip is filled with saliva.

6.



Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall 3 times to release the antigen in the swab.

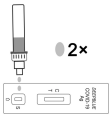
7.

Tighten the cap of the extraction tube clockwise.

8.

Unscrew the small white cap on the top of the extraction tube.

9.



Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer.

10.

Read result at 15 minutes. Do not read results after 30 minutes.

11.

Please put all used materials in the enclosed collection bag for proper disposal. The test kit can be disposed of with normal household waste in compliance with the applicable local regulations.

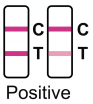
[Interpretation of test results]

Negative result:

Negative

If there is only a control line (C) and the test line (T) is colorless, it indicates that SARS-CoV-2 antigen has not been detected and the result is negative.
If the test result is negative: Continue to comply with all applicable rules regarding contacts and protective measures. Even if the test is negative, there may be an infection. In case of doubt, repeat the test after 1-2 days because the coronavirus cannot be accurately detected at all stages of infection.

Positive result:



Positive

If both the control line (C) and the test line (T) appear, it indicates that SARS-CoV-2 antigen has been detected and the result is positive.
If the test result is positive:

- **Currently, there is a suspected infection of COVID-19.**
- **Contact your doctor or local health department immediately.**
- **Comply with local regulations, self-isolate and report according to local regulations.**
- **Perform PCR test for confirmation.**

Invalid result:

Invalid

If the control line (C) is not observed, the test is considered to be invalid whether the test line (T) is visible or not. A new test needs to be performed using a new test device.
If the test result is invalid, it may be caused by incorrect test operation. Please repeat the test.
If the test result is still invalid, please contact your doctor or COVID-19 testing center.

[Summary]

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main Manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.
Once infected with the SARS-CoV-2 virus, you may be hospitalized and some complications may occur. If without prompt treatment it may even lead to death.

[Test principle]

This product uses the double antibody sandwich method to detect the SARS-CoV-2 N protein. When the sample contains the coronavirus antigen, both the test line (C) and the control line (T) will appear, and the result will be positive. When the sample does not contain the coronavirus antigen or no coronavirus antigen is detected, the test line (T) will not appear, only control line (C) will appear.

[Limitations of inspection methods]

1.This test kit is only used for in vitro diagnosis.
2.This test kit is only used to detect human saliva. The results of other specimens may be wrong.
3.This test kit is only used for qualitative detection and cannot indicate the level of SARS-CoV-2 antigen in the specimen.
4.This test kit is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.
5. This test does not determine the aetiology of the respiratory infection caused by micro-organisms other than the SARS-CoV-2 virus.
6.This test can detect both the viable and the non-viable SARS-CoV-2 virus. the accuracy of the test depends on the quality of the swab sample-false negative results may be given following poor sampling.
7.Any failure to respect the test procedure may negatively impact the performance of the test and/or invalidate the test result.
8.If the result of the test is negative, yet clinical symptoms persist, it is advised that you carry out additional tests using other clinical methods. A negative result at no time rules out the presence of antigens of the SARS-CoV-2 virus in the sample, as they may be present but at a level inferior to the minimum detection level of the test, or if the sample has been collected incorrectly.
9.A negative result does not rule out infection by the SARS-CoV-2 virus, particularly in people who have come into contact with the virus. Follow-up tests with molecular diagnostics should be scheduled to rule out infection in these people. Persons who show symptoms of the disease but have a negative result until infection is ruled out should follow country-specific restrictions.
10.This test is not a substitute for a medical consultation, or for the result of a biological analysis carried out in a medical analysis laboratory.
11. Positive test results do not exclude the possibility of co-infections of other pathogens.

[Warnings and Precautions]

1. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
2. Do not eat, drink, chew gum, smoke or vape for at least 30 minutes before collecting saliva. False negative results can occur if the saliva is not collected properly.
3. Guard against moisture, do not open the aluminum platinum bag before it is ready for testing. Do not use it if the aluminum foil bag is damaged or the test device is damp.
4. Please use it within the validity period.
5. Do not replace the components in this kit with components in other kits.
6. Do not dilute the specimen when testing, otherwise you may get inaccurate results.
7. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
8. The test methods and results must be interpreted in strict accordance with this specification.
9. Negative results may occur if the SARS-CoV-2 antigen titer in the specimen falls below the minimum detection limit of this kit.
10.If the extraction reagent is individual packing and one piece per test device, the batch number, expiration date and other information cannot be marked separately due to the space is limited, but those information will be consistent with the corresponding test kit.
11.There is no reduction in sensitivity in the Deepblue Antigen test against the UK variant, Brazilian variant or the South African variant.

[Storage conditions & period of validity]

1. Store at 4℃~30℃, and it is valid for 24 months.
2. After the aluminum foil bag is unsealed, the test device should be used as soon as possible and within one hour (15 ~ 30℃, Humidity ≤70%).

[Sample Transport and Storage]

Freshly collected specimens should be processed as soon as possible. It should be no later than one hour after collection.The processed specimens could be stored at 2-8℃ for no more than 24 hours.

[Quality Control]

Program control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient volume of the specimen.

[Performance index]

1. **Limit of detection (LOD):** $TCID_{50}$/mL is 80.
2. **High Dose Hook Effect:** When the virus concentration exceeds 1.4 x 10^5 $TCID_{50}$/mL, the result may be false negative.
3. **Cross-reactivity:** There is no cross-reactivity, including human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, human coronavirus HKU1, MERS-coronavirus, SARS coronavirus, adenovirus 3, and parainfluenza virus type 2, Enterovirus, respiratory syncytial virus (A), parainfluenza virus type 3, parainfluenza virus type 4a, influenza A H3N2 (Wisconsin/67/05), influenza A H1N1, influenza B (VICRTORIA), Rhinovirus (HRVA30), Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bacillus pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumonia, Mycobacterium tuberculosis, Pneumocystis, Pseudomonas Bacteria, human pneumonia virus (hMPV), parainfluenza virus type 1, Staphylococcus epidermidis, Streptococcus salivarius, etc.
4. **Microbial Interference Studies:** There is no interference in studies on the following microorganisms or pathogens, including parainfluenza virus type 1, parainfluenza virus type 2, parainfluenza virus type 3, parainfluenza virus type 4a, adenovirus, human pneumonia virus (hMPV), A H3N2 Influenza (Wisconsin/67/05), H1N1 influenza, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, influenza B (Malaysia/2506/04), enterovirus, respiratory syncytial virus, Rhinovirus, Chlamydia pneumoniae, Legionella pneumoniae, Mycobacterium tuberculosis, Pneumocystis, Pseudomonas, Candida albicans, Bacillus pertussis, Mycoplasma pneumoniae, Staphylococcus epidermidis, Streptococcus salivarius, human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, human coronavirus HKU1, MERS coronavirus, etc.
5. **Endogenous Interference Studies**: There is no interference in studies on the following substances, including blood, mucin, Alkalol, dexamethasone, Neilmed, benzocaine, oseltamivir, tobramycin, mupirocin, biotin, etc.

[Clinical Performance]

The overall study scale was 510 cases, 105 positive samples and 405 negative samples.

Statistics of test results of saliva samples:

Reference RT-PCR Assay							95% Wilson Score CI	
							LCI	UCI
DEEP BLUE SARS-CoV-2 Ag Test		POS	NEG	TOTAL	PPA	97.1%	90.8%	98.2%
	POS	102	1	103	NPA	99.8%	94.4%	99.9%
	NEG	3	404	407	PPV	99.1%	93.7%	99.8%
	TOTAL	105	405	510	NPV	99.3%	93.5%	99.7%

Sensitivity: 97.1% (95% CI: 90.8% - 98.2%)
Specificity: 99.8% (95% CI: 94.4% - 99.9%)
Sensitivity: Compared with the RT-PCR Assay, among people infected with SARS-CoV-2 virus, the probability of correct detection by the DeepBlue SARS-CoV-2 Ag Test Kit.
Specificity: Compared with the RT-PCR Assay, among people who have not been infected with SARS-CoV-2 virus, the probability of correct detection by the DeepBlue SARS-CoV-2 Ag Test Kit.

[Index of Symbols]

IVD	The product is used in vitro		Do not re-use		Avoid excessive exposure to the sun
	Expire date		Please read the instruction for use carefully before using		Date of manufacture
	Warning, please refer to the instructions in the package		Manufacturer		Don't use the product when the package is damaged
	Temperature range of product storage	LOT	Batch number	Σ	Contain sufficient quantity for <n> tests

EC REP	European union authorization representative		Keep dry

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.
4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone,230088 Hefei, Anhui, China.

EC REP

LUXUS LEBENSWELT GMBH
Kochstr. 1, 47877, Willich, Germany

UK Responsible Person

Lotus Global Co Ltd
23 Maine Street, Reading, RG2 6AG, England, United Kingdom.
E-mail:peter@lotusglobaluk.com

Swab Information

Shenzhen KangDaAn Biological Technology co.,LTD.
East-1, 3rd floor, Building 2, Shunheda factory, Liuxiandong industrial zone, Xili street, Nanshan district, Shenzhen China.

Goodwood Medical Care Ltd.
1-2Floor,3-919 Yongzheng Street Jinzhou Districet,Dalian,China.

Specification	**REF**
1 piece per box	SL030101SST-1
2 piece per box	SL030101SST-2
3 piece per box	SL030101SST-3
5 pieces per box	SL030101SST-5
6 pieces per box	SL030101SST-6
7 pieces per box	SL030101SST-7
8 pieces per box	SL030101SST-8
9 pieces per box	SL030101SST-9
10 pieces per box	SL030101SST-10
11 pieces per box	SL030101SST-11
12 pieces per box	SL030101SST-12
15 pieces per box	SL030101SST-15
16 pieces per box	SL030101SST-16
17 pieces per box	SL030101SST-17
18 pieces per box	SL030101SST-18
19 pieces per box	SL030101SST-19
20 pieces per box	SL030101SST-20
25 pieces per box	SL030101SST-25