DEEPBLUE

CE 1434

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

Self-testing

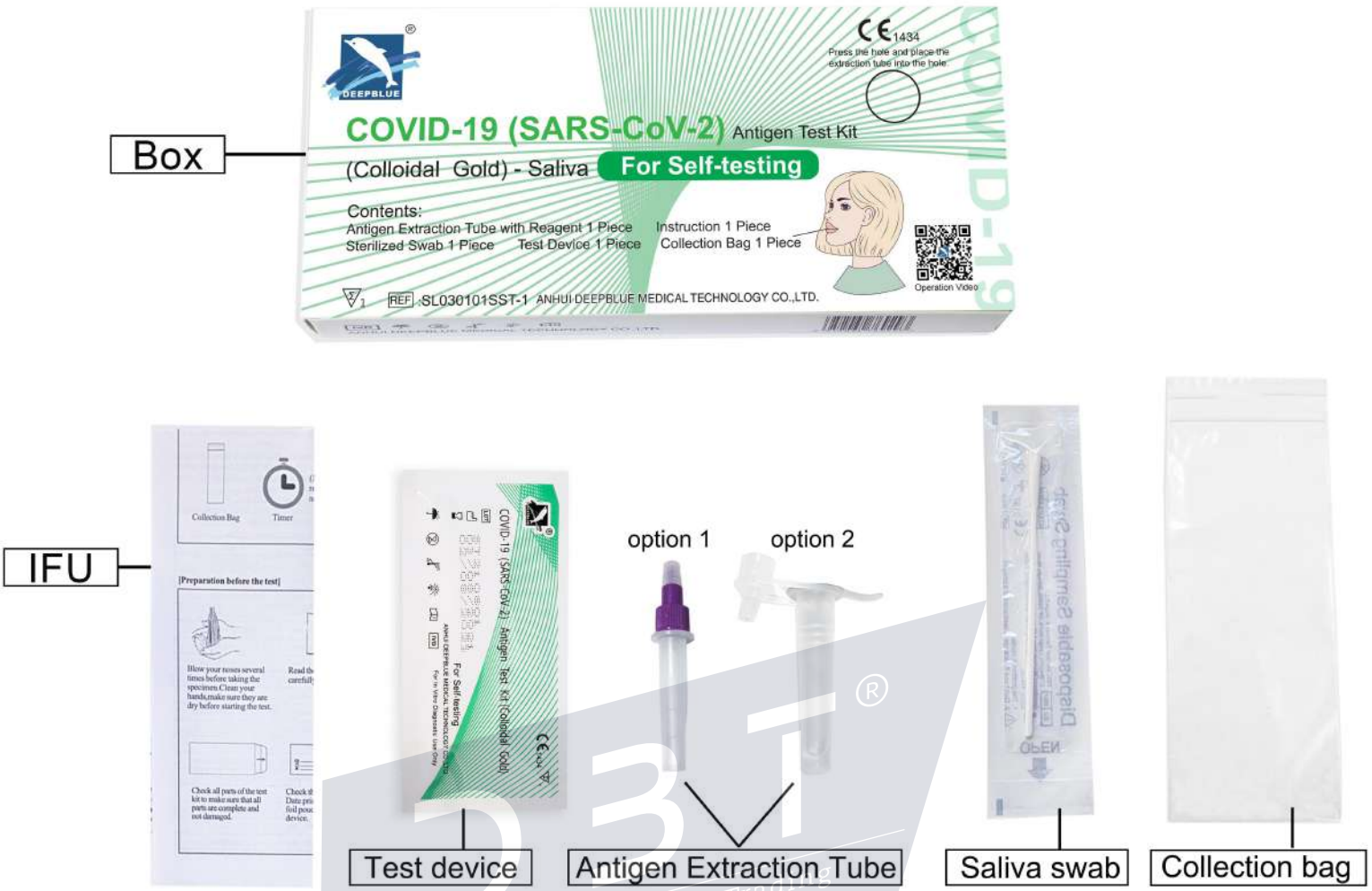
Anhui Deepblue Medical Technology Co.,Ltd.
Website:www.dbluemedical.com
Address:4th Floor D-1# Zone, Pearl Industrial Park 106 Innovation Avenue,High-Tech Development Zone 230088 Hefei, Anhui, China

1 pc / box,10 boxes / medium box, 45 medium box (450 Tests) / carton
Box size ：145*65*20mm
Medium box size ： 205*150*68mm,
Carton size: 63.5*47.5*36.5cm, G.W. 18.5kg

German version:1pc/box,800pcs/carton， carton size:61*54*55cm, G.W. 24.5KG

5 pcs / box 200 boxes /carton --1000 Tests /carton
Box size：130*70*52mm
Carton size: 55*54*37cm, G.W. 17.5kg

25 pcs / box 50 boxes /carton --1250 Tests /carton
Box size :260*120*75mm
Carton size: 62*54*40cm, G.W. 22.5kg



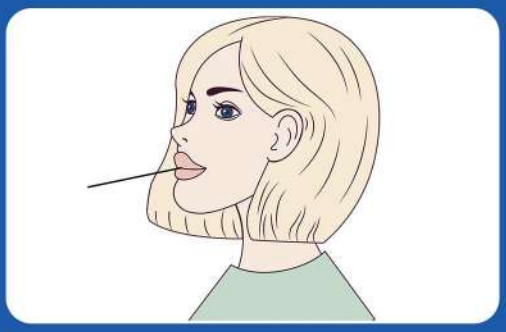
Your kit contains the following materials

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

DEEPBLUE

CE 1434

COVID-19 (SARS-CoV-2) Antigen test kit (Colloidal Gold) - Saliva (Self-Testing)



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

PERFORMANCE

SENSITIVITY: 98.7% (95% CI: 92.33% - 99.07%)

SPECIFICITY: >99.9% (95% CI: 98.17% - 100%)

CE

ISO 13485:2016 Medical Devices

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.

UK GOVERNMENT VALIDATED

The UK Government Public Health England, joint PHE Porton Down and University of Oxford was independently evaluated over 140 lateral flow devices that have been referred by the Department of Health and Social Care (DHSC) . Only a few can passed the phase 3A trials, and our DEEPBLUE even have passed phase 3B. That means our test has very high accuracy at multiple viral loads and able to detect the asymptomatic patients and the new different variants.

Easy to use

Using a saliva swab to collect the specimen in mouth, just like a lollipop.

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

Your kit contains the following materials

Test device

option 1 option 2

Antigen Extraction Tube

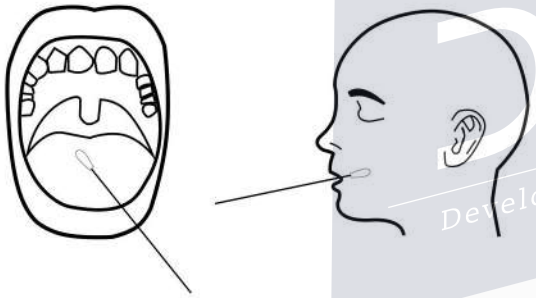
IFU

Saliva swab

Waste bag

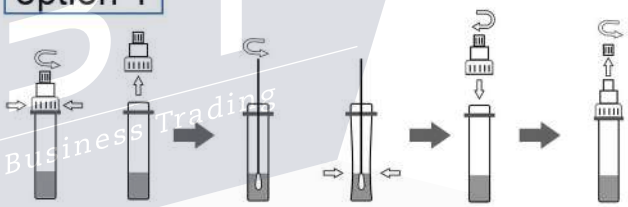
TEST PROCEDURE

1.Specimen Collection

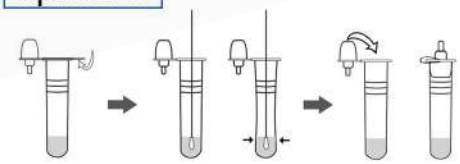


2.Specimen Preparation

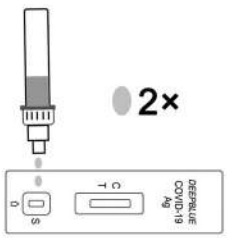
option 1



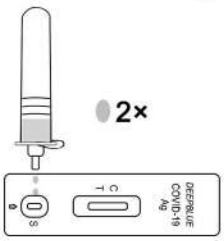
option 2



3.Testing



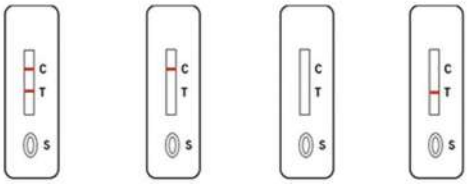
option 1



option 2

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.

4.Interpretation of test results



Positive Negative Invalid Invalid

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

CERTIFICATE

EC Certificate No. 1434-IVDD-484/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

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

in vitro diagnostic medical devices
for self-testing

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

(Colloidal Gold) – Saliva

The list of medical devices covered by this certificate is provided in the annex 1

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 10.11.2021 to 27.05.2024

The date of issue of the Certificate: 10.11.2021

The date of the first issue of the Certificate: 10.11.2021

CE 1434

Issued under the Contract No. MD-113/2021
Application No: 230/2021
Certificate bears the qualified signature.
Warsaw, 10.11.2021
Module A1

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.10 16:15:24 +01'00'

Vice-President

ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-484/2021

List of medical devices covered by the certificate:

DEEPBLUE, ShenLanTest, Highbluetest, NewBluetest, Quicklyblue

REF: SL030101SST-1, SL030101SST-2, SL030101SST-3, SL030101SST-4, SL030101SST-5, SL030101SST-6, SL030101SST-7, SL030101SST-8, SL030101SST-9, SL030101SST-10, SL030101SST-11, SL030101SST-12, SL030101SST-13, SL030101SST-14, SL030101SST-15, SL030101SST-16, SL030101SST-17, SL030101SST-18, SL030101SST-19, SL030101SST-20, SL030101SST-21, SL030101SST-22, SL030101SST-23, SL030101SST-24, SL030101SST-25

CE 1434

Issued under the Contract No. MD-113/2021
Application No: 230/2021
Certificate bears the qualified signature.
Warsaw, 10/11/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.10 16:16:26 +01'00'

Vice-President

www.dbluemedical.com

DECLARATION OF CONFORMITY

MANUFACTURER:	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
EUROPEAN REPRESENTATIVE:	Luxus Lebenswelt GmbH Kochstr. 1, 47877, Willich, Germany
PRODUCT:	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) -Saliva
Models:	SEE ATTACHMENT
REF:	SEE ATTACHMENT
CLASSIFICATION:	SELF-TESTING
EDMA CODE:	15 70 90 90 00

CONFORMITY ASSESSMENT ROUTE: Following the procedure relating to the EC Declaration of Conformity set out in Annex III Section 6 of Directive 98/79/EC.

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:	EN ISO 13485:2016 EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612: 2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975:2003, EN 13532:2002, EN ISO 14971:2012.
NOTIFIED BODY:	Polish Center for Testing and Certification 469 Puławska Street,02-844 Warsaw,Poland
(EN) CERTIFICATE(S):	1434-IVDD-484/2021
START OF CE-MARKING:	2021-11-10
PLACE, DATE OF ISSUE:	HEFEI, 2021-11-12

CE 1434

SIGNATURE: **CHEN FENGLING**

GENERAL MANAGER

www.dbluemedical.com

DECLARATION OF CONFORMITY ATTACHMENT

DEEPBLUE, ShenLanTest, Highbluetest, NewBluetest, Quicklyblue

Specification	REF
1 piece per box	SL030101SST-1
2 pieces per box	SL030101SST-2
3 pieces per box	SL030101SST-3
4 pieces per box	SL030101SST-4
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
13 pieces per box	SL030101SST-13
14 pieces per box	SL030101SST-14
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
21 pieces per box	SL030101SST-21
22 pieces per box	SL030101SST-22
23 pieces per box	SL030101SST-23
24 pieces per box	SL030101SST-24
25 pieces per box	SL030101SST-25

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:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

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

TÜV®

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

.

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

TÜV®

No.IFU-COVID-19Ag-SST-01,Ver.A/5

CE 1434

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

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

Operation 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. The final diagnosis should be made by medical staff based on laboratory results and symptom analysis.
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 With Extraction Reagent | 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

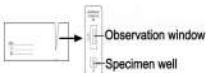
Check all parts of the test kit to make sure that all parts are complete and not damaged.

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

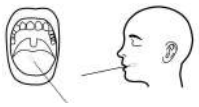
3.

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.

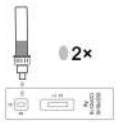
7.

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.

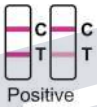
[Interpretation of test results]

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, and there is a possibility of false negatives for negative results.

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. Diarrhea is a very common symptom in children and young people.
Once infected with the SARS-CoV-2 virus, you may be hospitalized and some serious 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.
12. Do not swallow the extraction reagent. If accidentally touch the human skin, eyes or mucous membranes, please rinse with water immediately. If discomfort occurs, please consult a doctor.

[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 ≤80%).

[Sample Transport and Storage]

Freshly collected specimens should be processed as soon as possible. It should be no later than one hour after collection.

[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. This means that if the virus concentration in the body does not exceed this limit, the test result will be negative.
2. **High Dose Hook Effect:** When the virus concentration exceeds 1.4×10^5 $TCID_{50}$/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 600 cases, 150 positive samples and 450 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	98.7%	92.33%	99.07%
	POS	148	0	148	NPA	>99.9%	98.17%	100%
	NEG	2	450	452	PPV	>99.9%	98.17%	100%
	TOTAL	150	450	600	NPV	99.6%	92.76%	99.31%

Sensitivity: 98.7% (95% CI: 92.33% - 99.07%)
Specificity: >99.9% (95% CI: 98.17% - 100%)
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		Contain sufficient quantity for <n> tests
EC REP	European union authorization representative		Keep dry	CE 1434	CE Mark

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.