Bundesinstitut für Arzneimittel und Medizinprodukte

Paul-Ehrlich-Institut

Deepblue Covid-19 Antigen Lollitest

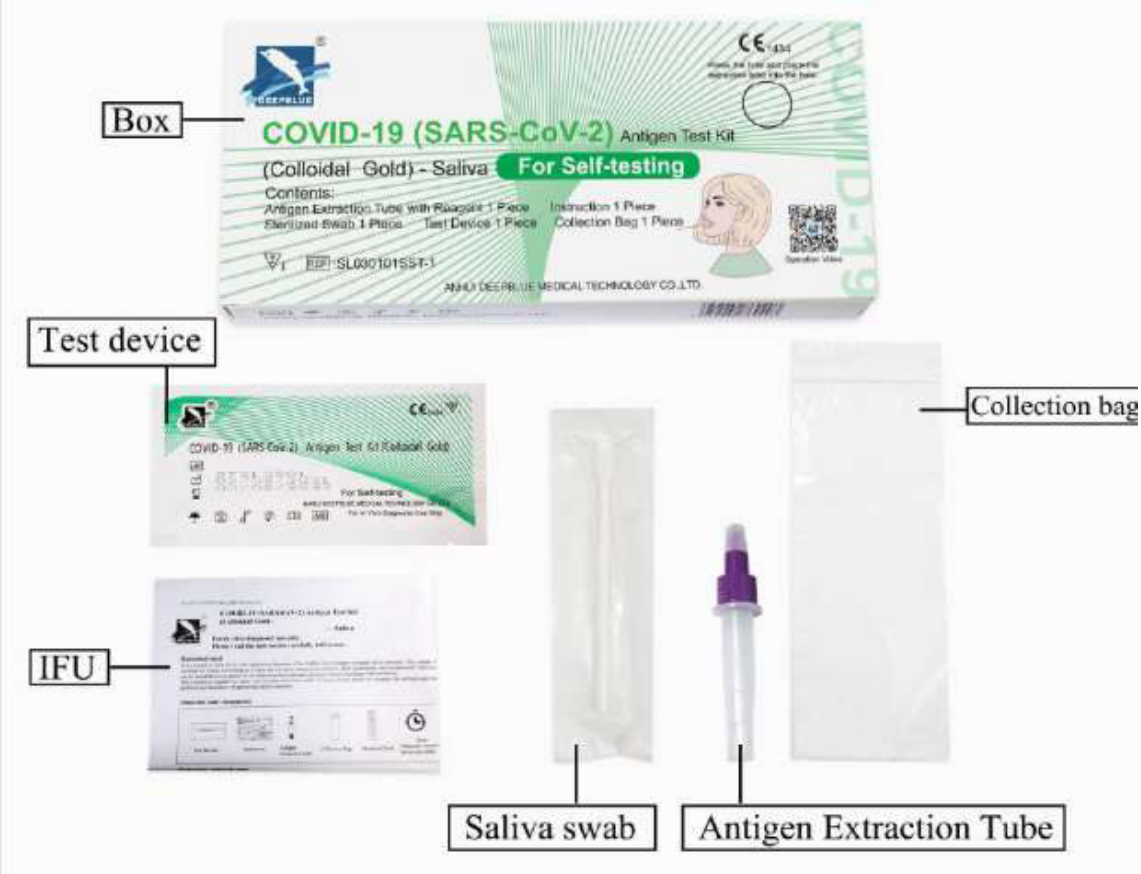
Laientest / Selbsttest mit CE1434 (1er verpackt)

Omikron-Variante (B.1.1.529, BA.4, BA.5) erkennen

geeignet für Kinder ab 0 Jahren alt

Hersteller	Anhui Deepblue Medical Technology Co.,Ltd.
Rep	Luxus Lebenswelt GmbH
CE	**CE1434 seit 10.11.2021**
BfArM Nummer	**AT1288/21**
Paul-Ehrlich-Institut	**evaluiert**
EU List	**Device #2651**
Empfindlichkeit	98,70%
Spezifität	99,99%
Genauigkeit	99,60%

Varianten (SKU)	**1er verpackt**
Inhalt pro Karton/VPE	**800 St.**
Abmessungen Karton	61x54x55cm; 26kg
Gebrauchsanleitung	auf Deutsch



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests auf SARS-CoV-2 zur Eigenanwendung

die Gegenstand des Anspruchs nach §1 Satz 1 Coronavirus-Testverordnung (TestV) sind („Selbsttests")

deep | Los | Aktionen

				Hersteller		Europäischer Bevollmä
Test-ID	Name des Tests	Evaluierung PEI	Omikron-Erkennung entsprechend der Bridging-Prüfung des PEI	Name	Land	Name
AT1288/21	COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold) - Speichel	Ja	Ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	CN	Luxus Lebenswelt GmbH

Comparative sensitivity evaluation for 122 CE-marked rapid diagnostic tests for SARS-CoV-2 antigen

RDT	Manufacturer	Test name	Sensitivity			
			Cq ≤ 25	Cq >25–<30	Cq ≥ 30	Cq 17–36
Subgroup of RDT with detection rates of 100% for Cq ≤25 and of >75% for Cq >25–<30						
54	Mölaboratory GmbH	mö-screen Corona Antigen Test	100.0%	47.8%	0.0%	58.0%
4	Affimedix	TestNOW - COVID-19 Antigen	100.0%	47.8%	0.0%	58.0%
55	MP Biomedicals Germany GmbH	Rapid SARS-CoV-2 Antigen Test Card	100.0%	43.5%	0.0%	54.0%
68	Qingdao Hightop Biotech Co., Ltd.	Hightop SARS-CoV-2 (Covid-19) Antigen Rapid Test	100.0%	43.5%	0.0%	54.0%
92	Xiamen Boson Biotech Co., Ltd	SARS-CoV-2 Antigen Schnelltest	100.0%	43.5%	0.0%	54.0%
27	DNA Diagnostic A/S.	Covid-19 Antigen Detection Kit	100.0%	39.1%	10.0%	54.0%
9	Anhui Deepblue Medical Technology Co., Ltd.	COVID-19 (SARS CoV-2) Antigen Test Kit (Colloidal Gold)	100.0%	39.1%	0.0%	52.0%
28	Edinburgh Genetics Limited	Edinburgh Genetics ActivXpress +	100.0%	34.8%	0.0%	50.0%

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
Website:http://www.dbluemedical.com/
Address:4th Floor D-1# Zone, Pearl Industrial Park 106 Innovation Avenue,High-Tech Development Zone 230088 Hefei,Anhui,China

Statement

We, Anhui Deepblue Medical Technology Co., Ltd located at 4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,High-Tech Development Zone,230088 Hefei, Anhui,China are here by to declare:

As the manufacture of the product:

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

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

COVID-19 (SARS-CoV-2) Antigen Test Midstream — Saliva

Would like to declare that the products are mainly use two antibody raw materials, the names and details are listed as follows:

No.	Material Name	Cat.	Material performance
1	2019-nCoV Nucleocapsid Antibody	NP-19	Concentration>1.0mg/mL, purity>90%
2	2019-nCoV Nucleocapsid Antibody	NP-33	Concentration>1.0mg/mL, purity>90%

The COVID-19 antigen test kits produced by our company have been verified by in-silico analysis and related experiments. The results showed that our product can effectively detect the following mutant strains (including but not limited to) without performance changes:

Variant	Pango lineage	Emergence
Alpha	B.1.1.7	UK
Beta	B.1.351	South Africa
Delta	B.1.617.2	India
Kappa	B.1.617.1	India

Gamma	P.I	Brazil
Zeta	P.2	Brazil
Lambda	C.37	Peru
Iota	B.1.526	USA
Eta	B.1.525	Multiple countries
Mu	B.1.621	Columbia
Omicron	BA.I	USA
Omicron	BA.2	UK
Omicron	XE	UK
Omicron	BA.4	UK、South Africa
Omicron	BA.5	South Africa

Our company will continue to pay attention to the mutation of the novel coronavirus, and will continue to track the detection of the mutant strain of the novel coronavirus. The relevant information will be updated and announced timely.

Company name: Anhui Deepblue Medical Technology Co., Ltd.

Date: May 24, 2022

Sign:

Stamp:

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

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
Website:http://www.dbluemedical.com/
Address:4th Floor D-1# Zone, Pearl Industrial Park 106 Innovation Avenue,High-Tech Development Zone 230088 Hefei,Anhui,China

Statement

With the development of the pandemic, new variants of the SARS-CoV-2 have been reported all over the world.

For the effective control of the pandemic, rapid and accurate screening of the target SARS-CoV-2 including the new occurred variants is of great significance.

Currently, the new variant, which is defined as Omicron (B.1.1.529), has been found in South Africa.

The variant sites of B.1.1.529 located main in the Spike proteins of SARS-CoV-2. According to the research, among the 50 variant sites, there are more than 30 variant sites located in the Spike protein, which induce 43 amino acid mutated residues in the Spike protein. Meanwhile, there are also some variant sites to the N protein. And these variant sites in N protein are not in the critical sites.

The detection target of the DEEPBLUE COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) is the N protein of SARS-CoV-2. The recognition site of our Antigen Test Kit locates in the site 45-187 of N protein. The new occurred variant Omicron of SARS-CoV-2 will not affect the screen results of the kit. The detection performance of our COVID-19 (SARS-CoV-2) Antigen Test Kit including the sensitivity and specificity can be well guaranteed. And we will also continue pay attention to the variants of the SARS-CoV-2 and make the update on the website.

Anhui DeepBlue Medical Technology Co. Ltd.
30/11/2021

30/11/2021

安徽深蓝医疗科技股份有限公司
ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

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

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

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

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

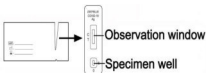
Check all parts of the test kit to make sure that all parts are complete and not damaged.

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

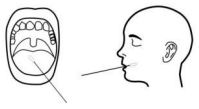
3.

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.

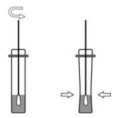
Remove the sterilized swab from the packaging.

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.

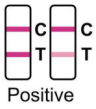
[Interpretation of test results]

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:

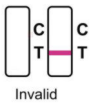


Positive

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.
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