



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](http://www.dbluemedical.com)  
Address:4th Floor D-1# Zone, Pearl Industrial Park 106  
Innovation Avenue,High-Tech Development Zone 230088 Hefei,  
Anhui, China



1pc/box, 800pcs/carton

Box size : 145\*65\*20mm

arton size: 61\*54\*55cm, G.W. 22.5 KG



5pcs / box      200boxes /carton --1000Tests/carton

Box size : 130\*70\*52mm

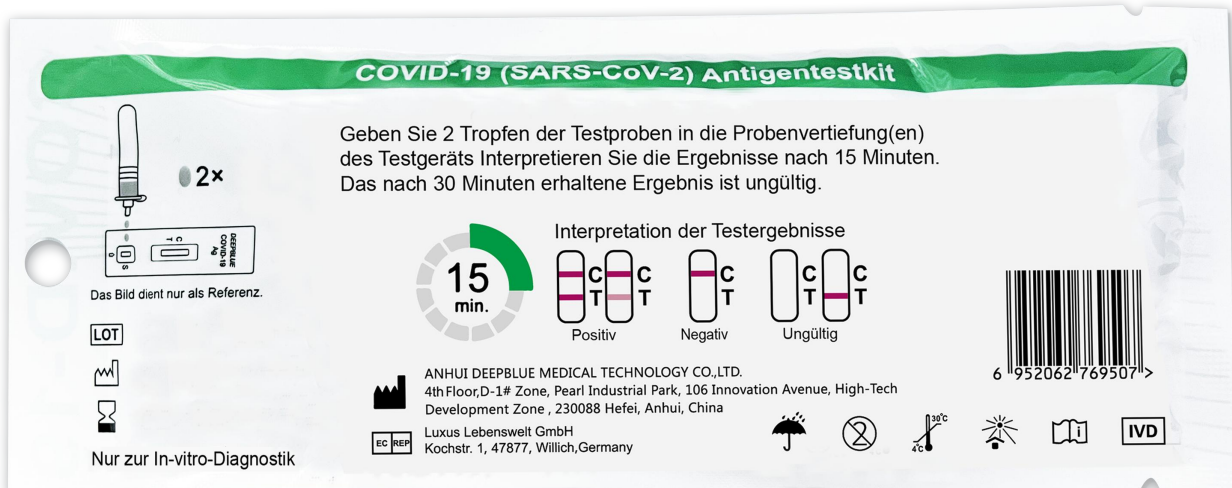
Carton size:55\*54\*37cm,G.W.16.5kg



25 pcs / box 50 boxes /carton --1250 Tests /carton

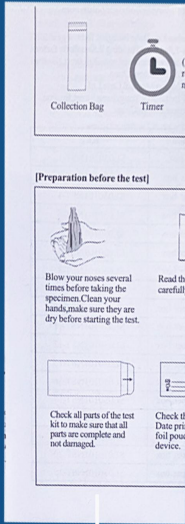
Box size :260\*120\*70mm

Carton size: 62\*54\*38cm, G.W. 18.5 kg



One test in one soft bag, 25 pcs per ziplock bag, 1000 pcs per carton, carton size: 62\*54\*45cm, G.W. 20 kg

Box



IFU



Test device



Antigen Extraction Tube



Saliva swab



Collection bag

## Your kit contains the following materials

Box

IFU

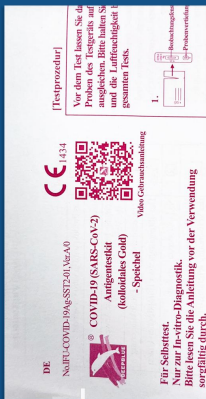
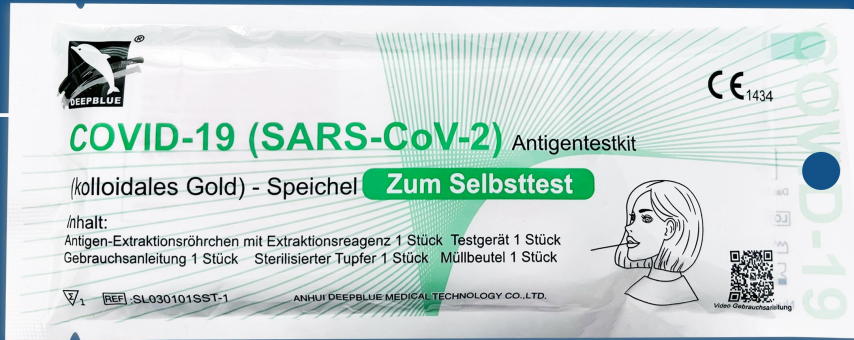
Saliva swab

Test device

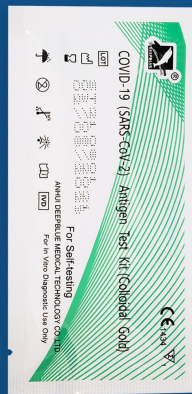
Collection bag

Antigen Extraction Tube

Bag



IFU



Test device



Antigen Extraction Tube



Saliva swab



Collection bag

## Your kit contains the following materials

Bag

IFU

Saliva swab

Test device

Collection bag

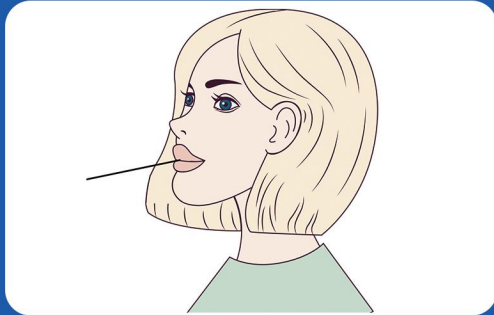
Antigen Extraction Tube

Soft package with minimum size and weight, suitable for supermarket or Pharmacy to hang it on the shelf.



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°C

## PERFORMANCE

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

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



## PRODUCT ADVANTAGES

- ◆ Sterilized aluminum foil sealing pre-filled buffer solution, minimum leaking risk, easier operation.
- ◆ Passed the PEI evaluation.
- ◆ Room temperature storage.
- ◆ No need instrument, get results within **15 minutes**.
- ◆ Identify acute or early infection.
- ◆ No reduction in sensitivity test against **the Alpha, Beta, Delta, Gamma, Lambda, Omicron variant and so on**.

## 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

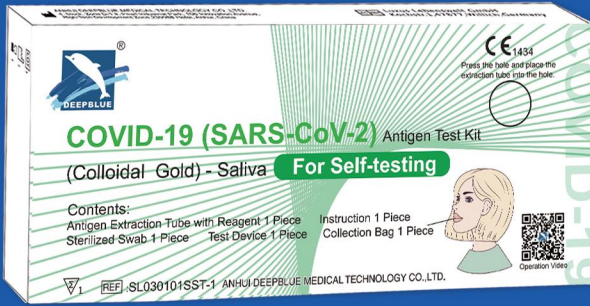
Using a saliva swab to collect the specimen in mouth, just like a lollipop.



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



# Your kit contains the following materials



Test device

Antigen Extraction Tube

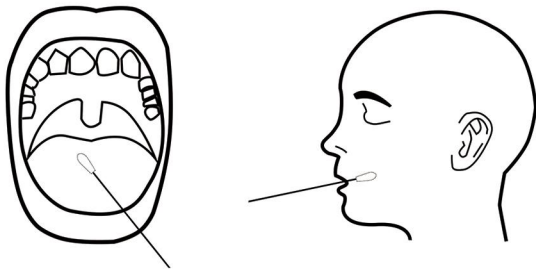
IFU

Saliva swab

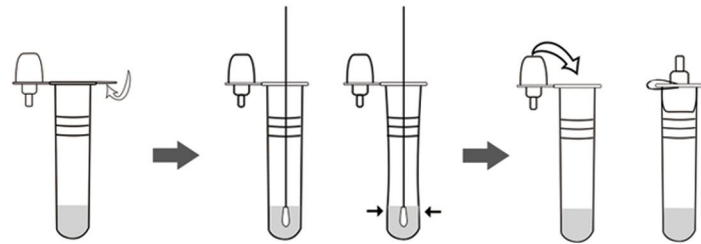
Waste bag

## TEST PROCEDURE

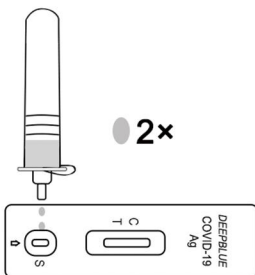
### 1. Specimen Collection



### 2. Specimen Preparation

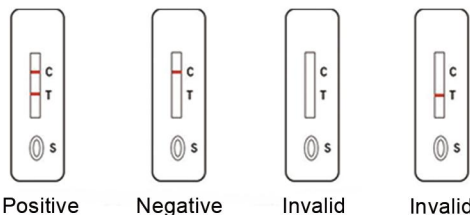


### 3. Testing



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.

### 4. Interpretation of test results

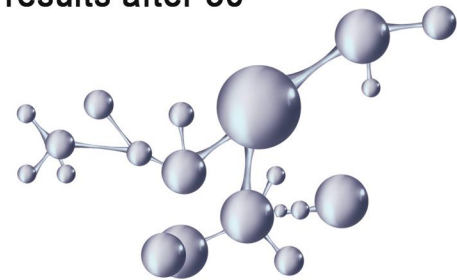


Positive

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](http://www.dbluemedical.com) 【Contact】 0551-65326797



# Your kit contains the following materials



Test device

Antigen Extraction Tube

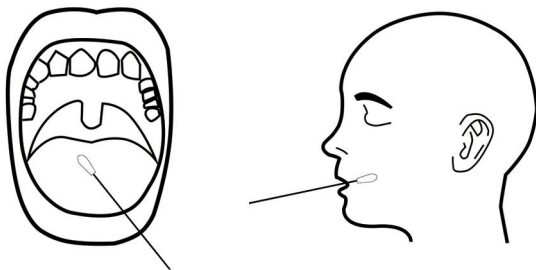
IFU

Saliva swab

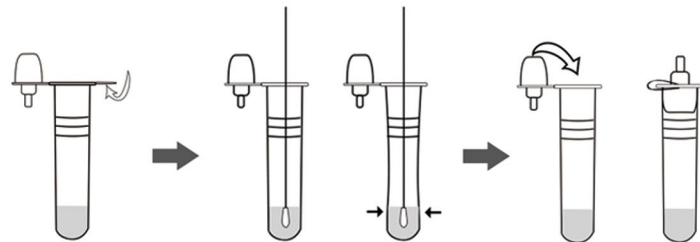
Waste bag

## TEST PROCEDURE

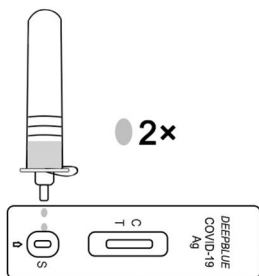
### 1. Specimen Collection



### 2. Specimen Preparation

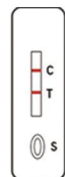
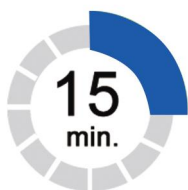


### 3. Testing

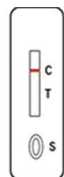


Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer. Interpret the results at 15 minutes, and the results after 30 minutes are no longer valid.

### 4. Interpretation of test results



Positive



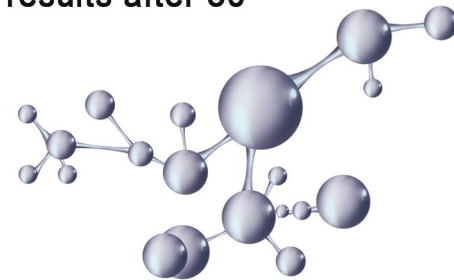
Negative



Invalid



Invalid



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【Website】 [www.dbluemedical.com](http://www.dbluemedical.com) 【Contact】 0551-65326797

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

Allgemeine Hinweise

ANHUI DEEPBLUE

Los

Aktionen

Zurücksetz

Nach 'ANHUI DEEPBLUE' suchen

Test-ID	Name des Tests	Evaluieru... PEI	Hersteller		Europäischer Bevollmächtigter		Probennahme
			Name ↑≡	Land	Name	Land	
AT1288/21	COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold) - Speichel	Nein	ANHUI DEEPBLUE MEDICAL TEC...	CN	Luxus Lebenswelt GmbH	DE	Speichel
AT1190/21	COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold)	Ja	ANHUI DEEPBLUE MEDICAL TEC...	CN	Luxus Lebenswelt GmbH	DE	nasal

1 1 - 2 v

letzte Änderung: 02.12.2021 09:45

## Germany BfArM Self Test List

Name des Tests	Evaluieru... PEI	Hersteller	
		Name ↑≡	Land
COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold)	Ja	ANHUI DEEPBLUE MEDICAL TEC...	CN
COVID-19 (SARS-CoV-2) Antigentestkit (kolloidales Gold) - Speichel	Ja	ANHUI DEEPBLUE MEDICAL TEC...	CN

Passed the PEI evaluation.

Hersteller		Europäischer Bevollmächtigter			Sensitivität		Spezifität	
Land	Name	Land	Probennahme	%	95%iges Vertrauensin...	%	95%iges Vertrauensin...	
CN	Luxus Lebenswelt GmbH	DE	nasal	96,40	90,8 - 98,2	99,80	94,4 - 99,9	
CN	Luxus Lebenswelt GmbH	DE	Speichel	98,70	92,33 - 99,07	99,90	98,17 - 100	

Performance :

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

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



# 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



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  
Vice-President

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



www.dbluemedical.com

## DECLARATION OF CONFORMITY

**MANUFACTURER:** ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.  
4<sup>th</sup> 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

**SIGNATURE:** CHEN FENGLING

**GENERAL MANAGER**



EC Declaration of Conformity

DOC-COVID-19 Ag(M/0)



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





# 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](http://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



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