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

DEEPBLUE

CE 1434

COVID-19 (SARS-CoV-2) Antigentestkit

(kolloidales Gold) - Speichel **Zum Selbsttest**

Inhalt:
Antigen-Extraktionsröhrchen mit Extraktionsreagenz 1 Stück Testgerät 1 Stück
Gebrauchsanleitung 1 Stück Sterilisierter Tupfer 1 Stück Müllbeutel 1 Stück

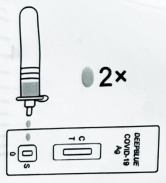


Video Gebrauchsanleitung

1 REF :SL030101SST-1 ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

COVID-19

COVID-19 (SARS-CoV-2) Antigentestkit



2×

Das Bild dient nur als Referenz.

Geben Sie 2 Tropfen der Testproben in die Probenvertiefung(en) des Testgeräts Interpretieren Sie die Ergebnisse nach 15 Minuten. Das nach 30 Minuten erhaltene Ergebnis ist ungültig.

LOT ST211203
03/12/2021
02/12/2023

Nur zur In-vitro-Diagnostik

15 min.

Interpretation der Testergebnisse



6 952062 769507



Bag size ：200*80 mm

Carton size: 61*54*45cm　　1200 pcs /carton



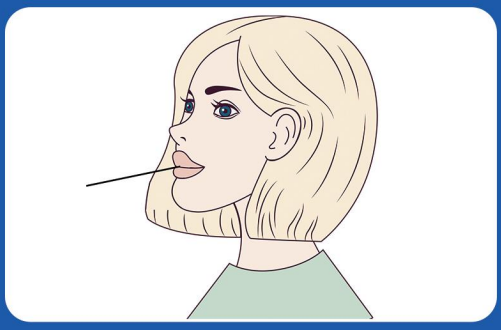
Your kit contains the following materials

- Bag
- 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/bag
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



Antigen Extraction Tube



IFU



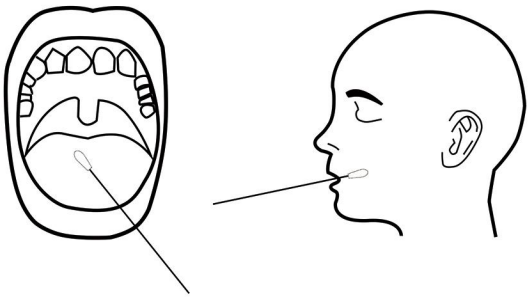
Saliva swab



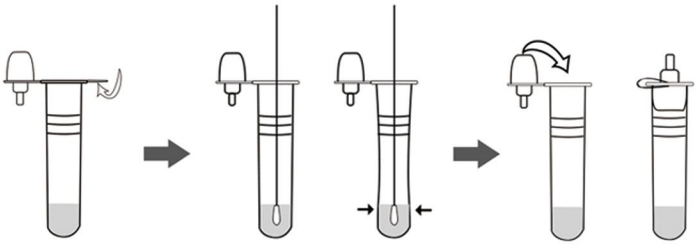
Waste bag

TEST PROCEDURE

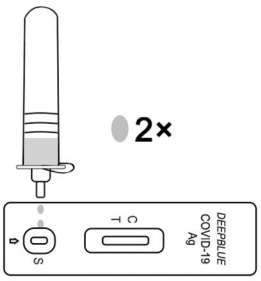
1.Specimen Collection



2.Specimen Preparation

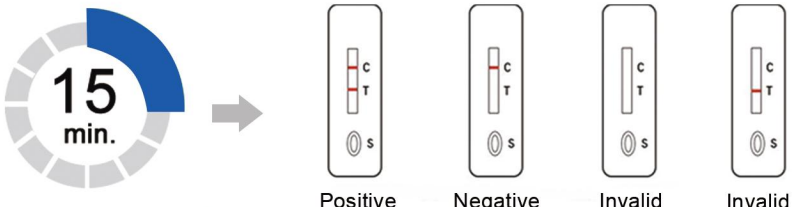


3.Testing



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 【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:

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):

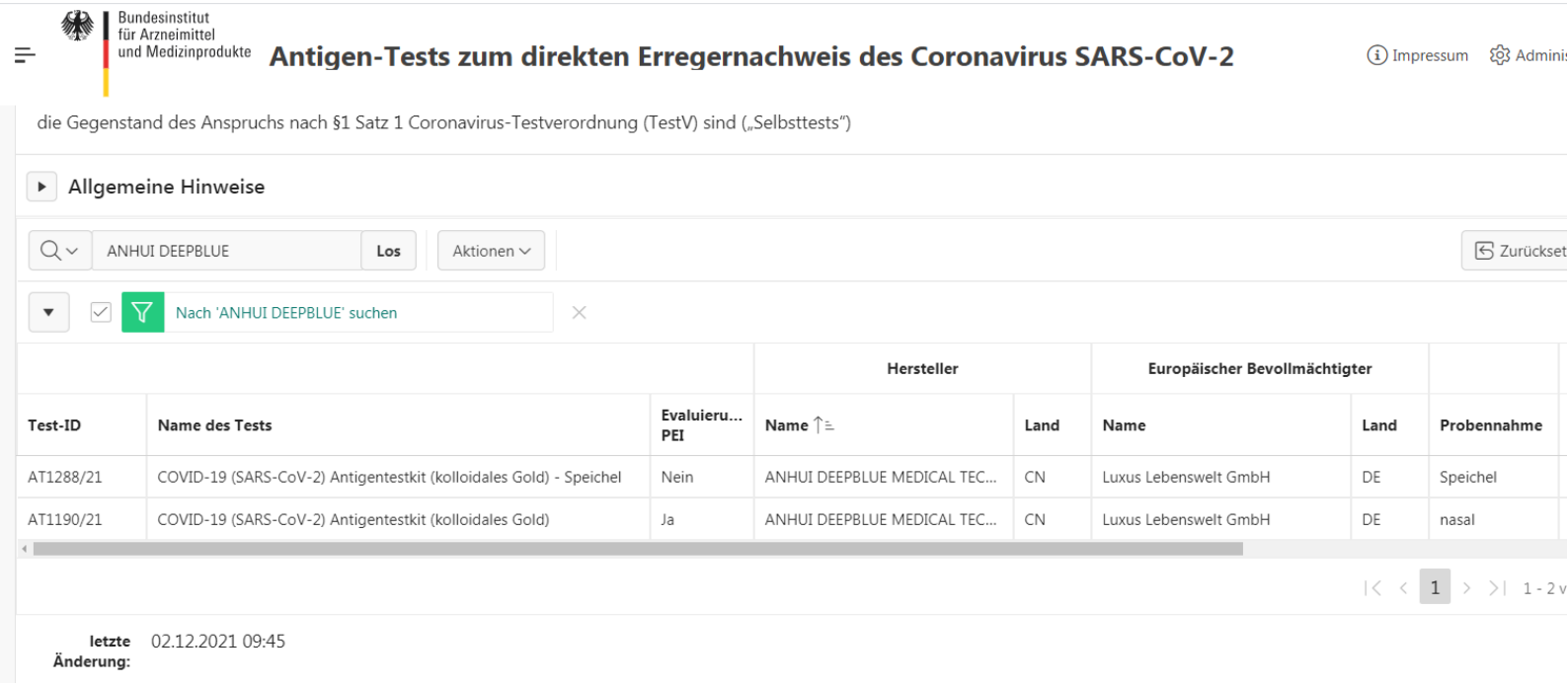
ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

.

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

TÜV®



Bundesinstitut für Arzneimittel und Medizinprodukte

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

Impressum Adminis

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

Allgemeine Hinweise

ANHUI DEEPBLUE | Los | Aktionen | Zurückset

Nach 'ANHUI DEEPBLUE' suchen

			Hersteller		Europäischer Bevollmächtigter		
Test-ID	Name des Tests	Evaluieru... PEI	Name	Land	Name	Land	Probennahme
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 - 2 v

letzte Änderung: 02.12.2021 09:45

Germany BfArM Self Test List