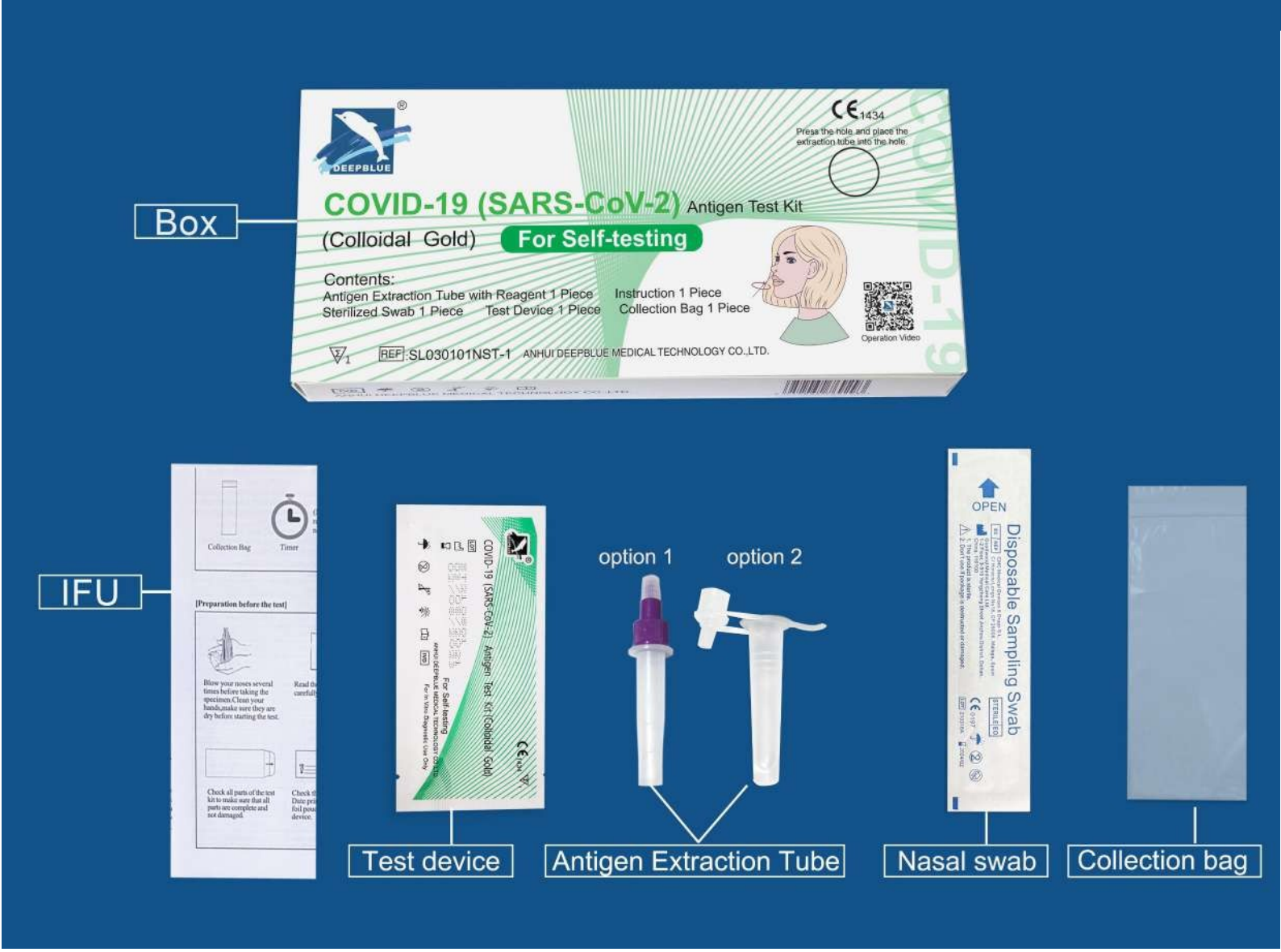
DEEPBLUE

CE 1434

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

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.



Your kit contains the following materials

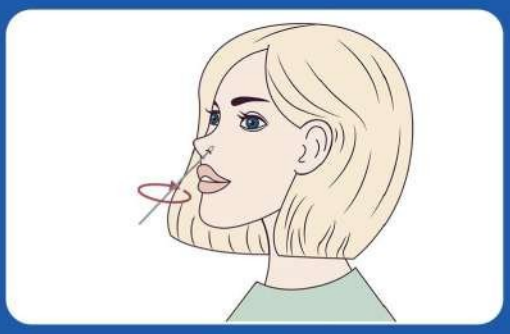
- Box
- IFU
- Nasal swab
- Test device
- Collection bag
- Antigen Extraction Tube

DEEPBLUE

CE 1434

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

(Self-Testing)



Specification	1 pcs/box 5 pcs/box 25 pcs/box
Specimen	Human Anterior Nasal Swab
Storage	4~30℃

PERFORMANCE

SENSITIVITY: 96.4%(95%CI: 90.8%-98.2%)

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

MHRA

Department of Health & Social Care

CE

ISO 13485:2016 Medical Devices

European Commission

EU HSC mutual recognition (RAT)

PRODUCT FEATURES

- Pre-filled buffer solution, 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 simple nasal swab within 2cm of the nose makes it extremely easy to administer.

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

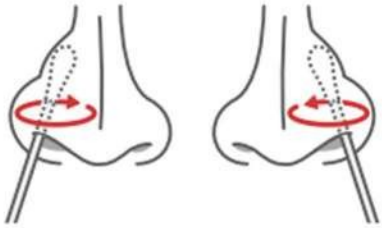
IFU

Nasal swab

Waste bag

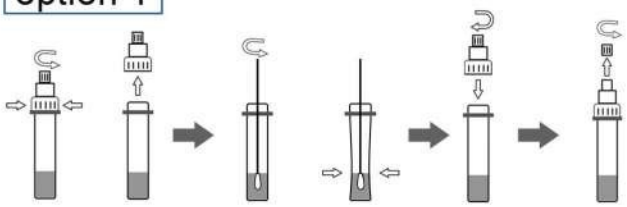
TEST PROCEDURE

1.Specimen Collection

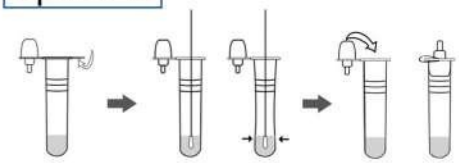


2.Specimen Preparation

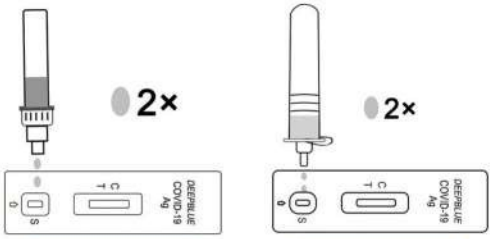
option 1



option 2

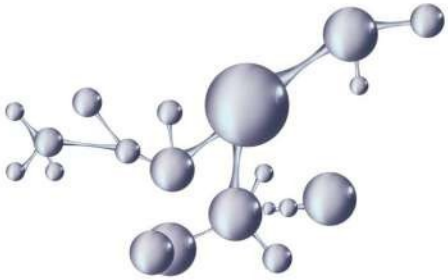


3.Testing

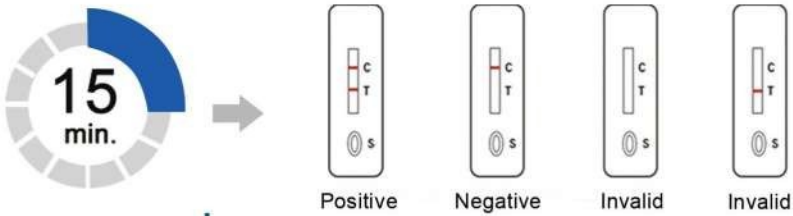


option 1 option 2

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-445/2021

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)

SL030101NST-1,SL030101NST-2, SL030101NST-3, SL030101NST-5, SL030101NST-6, SL030101NST-7, SL030101NST-8, SL030101NST-9, SL030101NST-10, SL030101NST-11, SL030101NST-12, SL030101NST-15, SL030101NST-16, SL030101NST-17, SL030101NST-18, SL030101NST-19, SL030101NST-20, SL030101NST-25

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 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 22.07.2021

CE 1434

Issued under the Contract No. MD-96/2021
Application No: 183a/2021
Certificate bears the qualified signature.
Warsaw, 30.07.2021
Module A1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.07.30 10:31:11 +02'00'
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)
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 Article 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-445/2021
START OF CE-MARKING:	2021-07-30
PLACE, DATE OF ISSUE:	HEFEI, 2021-10-27

CE 1434

SIGNATURE: **CHEN FENGLING**

GENERAL MANAGER

EC Declaration of Conformity

DOC-COVID-19 Ag(P/1)

www.dbluemedical.com

DECLARATION OF CONFORMITY
ATTACHMENT

Specification	REF
1 piece per box	SL030101NST-1
2 pieces per box	SL030101NST-2
3 pieces per box	SL030101NST-3
5 pieces per box	SL030101NST-5
6 pieces per box	SL030101NST-6
7 pieces per box	SL030101NST-7
8 pieces per box	SL030101NST-8
9 pieces per box	SL030101NST-9
10 pieces per box	SL030101NST-10
11 pieces per box	SL030101NST-11
12 pieces per box	SL030101NST-12
15 pieces per box	SL030101NST-15
16 pieces per box	SL030101NST-16
17 pieces per box	SL030101NST-17
18 pieces per box	SL030101NST-18
19 pieces per box	SL030101NST-19
20 pieces per box	SL030101NST-20
25 pieces per box	SL030101NST-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

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®

ISO9001 certification

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00121Q310783R0M/3400

We hereby certify that

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.

Unified Social Credit Code: 913401005501903714

4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, Hefei City, AnHui Province, P.R.China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

GB/T 19001-2016 / ISO 9001:2015

The Quality Management System Applies in the following area:

Colloidal Gold and Enzymatic Chemical Reaction Method in Vitro Diagnostic Reagents, Medical Ultrasound Coupling Agent, Epithelial Tissue Staining Solution, Vaginitis Rapid detection Kit (Polyamine Method), Cell Preservation Solution, Virus Sampling Tube, Medical Ice Cap and Wound Dressing within the Scope of Qualification's Development and Production

Certified since: November 11, 2021 Valid from: November 11, 2021 Valid until: November 10, 2024

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.
Please access www.cqc.com.cn for checking validity of the certificate.
This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

CNAS 中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS C001-M

Signed by: Xie ZhaoXu

IQNet

CHINA QUALITY CERTIFICATION CENTRE 中国质量认证中心

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China
http://www.cqc.com.cn

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2021年版