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

1pc/box, 500pcs/carton

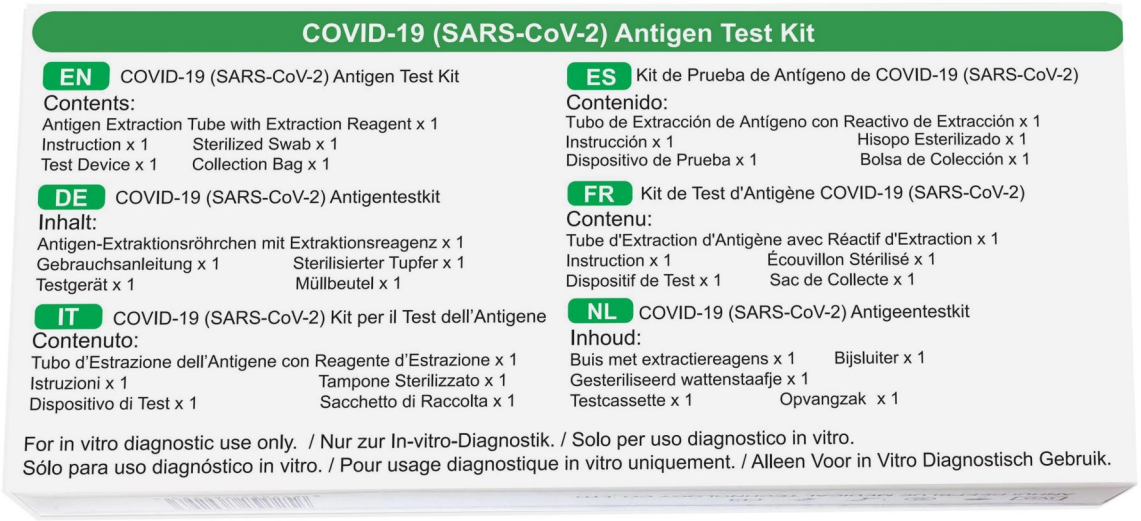
Box size：144*65*19mm

Carton size: 59.5*49.5*35cm, G.W. 14.5 kg

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

Box size：130*70*52mm

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



Multi language version: 1pc/box, 500pcs/carton

Box size：144*65*19mm

Carton size: 59.5*49.5*35cm, G.W. 14.5 KG

Scan QR code for Multi language IFU

Multi language box and Instruction For Use. Smooth circulation and distribution in multinational markets. Scan QR code and access to multi language IFUs, convenient and efficient.

Your kit contains the following materials

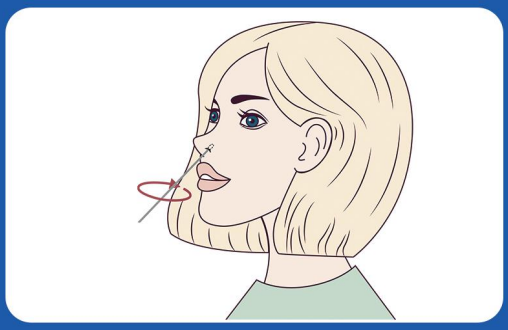
- Box*1
- IFU*1
- Nasal swab*1
- Test device*1
- Collection bag*1
- Antigen Extraction Tube*1

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

Antigen Extraction Tube

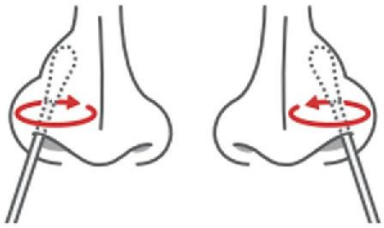
IFU

Nasal swab

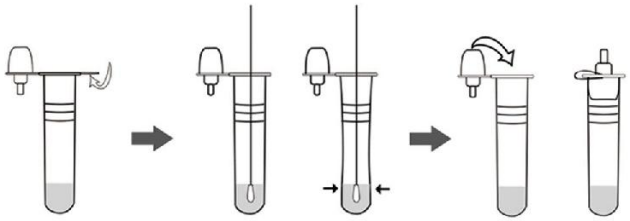
Waste bag

TEST PROCEDURE

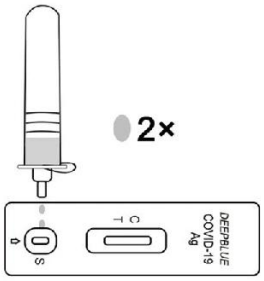
1.Specimen Collection



2.Specimen Preparation

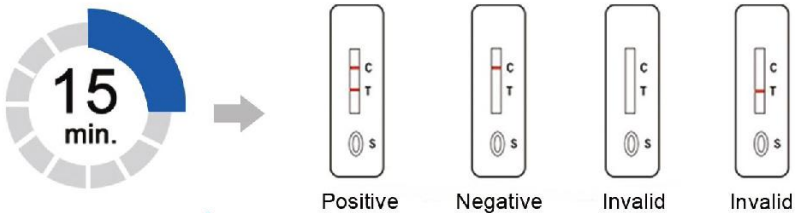


3.Testing

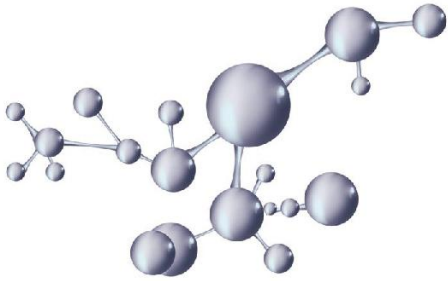


Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer. Interpret the results at 15 minutes, and the results after 30 minutes are no longer valid.

4.Interpretation of test results



Positive Negative Invalid Invalid



DEEPBLUE

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-055/2022

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 30.03.2022 to 27.05.2025

The date of issue of the Certificate: 30.03.2022

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, 30/03/2022
Module A1

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

WRITTEN CONFIRMATION TO IVDD CERTIFICATE

Manufacturer: **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
No. 777 Jimingshan Road, High-Tech Development Zone, 230088
Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA

IVDD certificate issuing Notified Body: Polish Centre for Testing and Certification (NB 1434)
IVDD certificate number: 1434-IVDD-055/2022
IVDD certificate issued to: Anhui Deepblue Medical Technology Co., Ltd.

Confirmation of the status of IVDD certificate in the framework of Regulation EU 2024/1860 amending Regulations (EU) 2017/746 as regards the transitional provisions for in vitro diagnostic medical devices.

This statement confirms that, Sertio Oy, a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 3018 on NANDO, has taken appropriate surveillance of the devices covered by the IVDD certificate listed below, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement with the manufacturer in accordance with Section 4.3, second subparagraph of Annex VII of IVDR. Based on these conditions, the manufacturer can benefit from transitional provisions according to EU amending regulation 2024/1860 for the above-mentioned devices. IVDD certificate is considered to remain valid provided that the manufacturer fulfils the following conditions:

- Continuous compliance of the device with the Directive 98/79/EC
- No significant changes in the design and intended purpose of the devices
- Registration of economic operators and of devices (see Art. 28 IVDR and Art. 26 IVDR)
- Post market surveillance (PMS) responsibilities (see Art. 78-81, 87 IVDR, MDCG 2022-8)
- Vigilance responsibilities (see Art- 82-87 IVDR)
- The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health

According to EU Regulation (EU) 2024/1860), this statement is valid at furthest:
- 31 December 2027, regardless of device risk class under the IVDR[1]

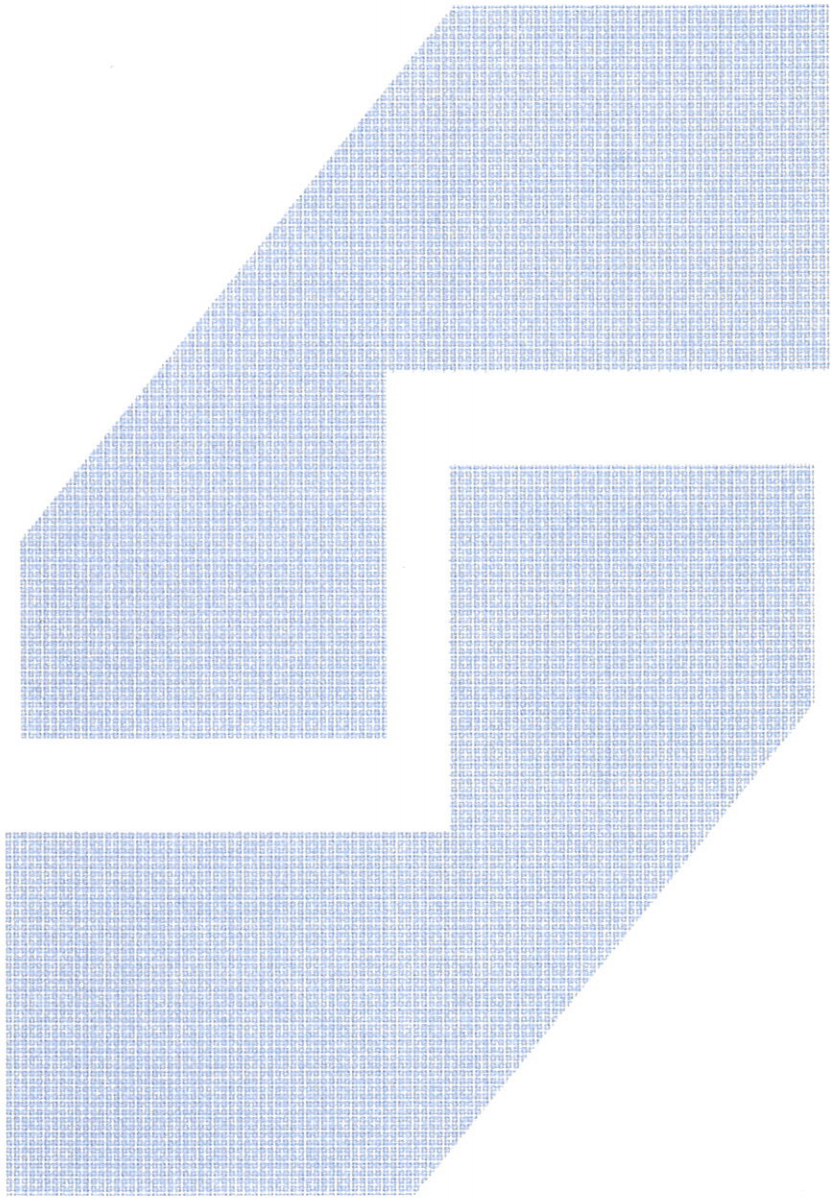
On behalf of the Notified Body,
Tampere, 26.5.2025

Mikko Soikkeli
Deputy Head of the Notified Body
Notified Body 3018
Biokatu 10, 33520 Tampere, Finland
info@sertio.fi
www.sertio.fi

[1] verify validity of written confirmation through info@sertio.fi

Written Confirmation Revision History

Date	NB internal reference traceable to each version	Action
26.5.2025	800030WC1-1	Initial issue



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. 03

Holder of Certificate: **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
No. 777 Jimingshan Road, 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 for Immunology, Immunochemistry, Clinical Chemistry, Samples Collection devices and Medical ultrasonic couplant**

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, Certification, Validation and Verification Regulations 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. 03

Report No.: SH24130302

Valid from: 2024-06-22
Valid until: 2027-06-21

Date, 2024-06-12

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

TÜV SÜD Product Service

Certificate

No. Q5 003706 0001 Rev. 03

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies): **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
No. 777 Jimingshan Road, 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®

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

America

CERTIFICATE

No. QS6 003706 0004 Rev. 00

Certificate Holder: **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
No. 777 Jimingshan Road, High-Tech Development Zone
230088 Hefei, Anhui
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Reagents for Immunochromatography, Immunochemistry, and Non-Sterile Sampling Collection Devices, Non-Sterile Medical Ultrasonic Couplant**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 003706 0004 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F007073**
Report No.: **SH23130302**
Effective Date: **2023-11-22**
Expiry Date: **2026-11-21**

Date of Issue: 2023-11-27

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 003706 0004 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
No. 777 Jimingshan Road, High-Tech Development Zone,
230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Reagents for Immunochromatography, Immunochemistry, and Non-Sterile Sampling Collection Devices, Non-Sterile Medical Ultrasonic Couplant
REPs Facility ID: F007073

Date of Issue: 2023-11-27

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

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).

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

Signed by: Xie ZhaoXu

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

A 0027986

2021年版

European Commission

Live, work, travel in the EU

COVID-19 In Vitro Diagnostic Devices and Test Methods Database

COVID-19 In Vitro Diagnostic Medical Device - detail

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

Manufactured by Anhui Deep Blue Medical Technology Co., Ltd, China - www.dbluemedical.com/

Device identification number
1815

CE Marking	✓ Yes
HSC common list	✓ Yes
HSC mutual recognition	✓ Yes
Format	Near POC / POC
Physical Support	Lateral flow
Target	Antigen

Specimen	Anterior nasal swab, Nasal swab
Commercial Status	Commercialised
Last Update	2021-07-07 05:18:58 CET

Comments

Please check attached UK national systematic evaluation report with the detailed data from UK government validation, performed by University of Oxford. Public Health England Porton Down. 132 brands were tested and only 4 suppliers have passed all of the Phase 3B validation, including ANHUI DEEPBLUE MEDICAL. The link of this report: https://www.medrxiv.org/content/10.1101/2021.01.13.21249563v1.full-text Please check attached UK national systematic evaluation report with the detailed data from UK government validation, performed by University of Oxford. Public Health England Porton Down. 132 brands were tested and only 4 suppliers have passed all of the Phase 3B validation, including ANHUI DEEPBLUE MEDICAL. The link of this report: https://www.medrxiv.org/content/10.1101/2021.01.13.21249563v1.full-text And we have attached the MHRA registration certificate. Also the registration in Germany, registration in Italy, registration in Portugal and so on.

Show HSC list status history

Germany BfArM Self Test List

Bundesinstitut für Arzneimittel und Medizinprodukte

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

Impressum Administration

Das BfArM stellt hier eine Liste nach §1 Satz 1 TestV der Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2 bereit, **die vom Hersteller zur Eigenanwendung zweckbestimmt sind („Selbsttests")** und nach Kenntnis des BfArM eine CE-Kennzeichnung tragen oder deren erstmaliges Inverkehrbringen in Deutschland ohne CE-Kennzeichnung vom BfArM nach §11 Abs.1 MPG derzeit befristet zugelassen wird („Sonderzulassung des BfArM").

Die Liste wird kontinuierlich aktualisiert, sobald seitens des BfArM weitere entsprechende Sonderzulassungen erteilt wurden, diese, z.B. durch Ablauf der Befristung der Sonderzulassung oder Abschluss der regulären Konformitätsbewertung und CE-Kennzeichnung, nicht mehr bestehen oder das Verfahren zur Aufnahme CE-gekennzeichneter Tests zur Eigenanwendung in die Liste erfolgreich abgeschlossen wurde.

Eine entsprechende Marktübersicht nach §1 Satz 1 TestV zu Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2, **die vom Hersteller zur professionellen Anwendung zweckbestimmt sind („Schnelltests")** finden Sie unter folgendem Link.

Weitere Hinweise zur vom BfArM bereitgestellten Liste sowie zu den der Sonderzulassung durch das BfArM, Aufnahme in die Liste und ggfs. auch Streichung von der Liste zugrundeliegenden Verfahren und Kriterien finden Sie auf unserer Webseite zu Antigentests auf SARS-CoV-2.

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

ANHUI DEEPBLUE MEDICAL | Los | Aktionen | Zurücksetzen

Nach 'ANHUI DEEPBLUE MEDICAL' suchen

			Hersteller		Europäischer Bevollmächtigter			Sensitivität		Spezifität		
Test-ID	Name des Tests	Evaluierung PEI	Name	Land	Name	Land	Probennahme	%	95%iges Vertrauensint...	%	95%iges Vertrauensint...	Gebrauchsanw...
AT1190/21	COVID-19 (SARS-CoV-2) Antigentest...	Ja	ANHUI DEEPBLUE MEDICAL TECHN...	CN	Luxus Lebenswelt GmbH	DE	nasal	96,40	90,8 - 98,2	99,80	94,4 - 99,9	Link öffnen

1 Zeilen ausgewählt 1 - 1 von 1

Germany BfArM Professional Use Test List

Bundesinstitut für Arzneimittel und Medizinprodukte

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

Impressum Administration

Alle Daten gemäß Übermittlung des Herstellers, verbindlich sind ausschließlich die Angaben in den jeweiligen Gebrauchsinformationen.

Die Angabe „Evaluierung PEI" bildet die entsprechende, auf der Webseite des Paul-Ehrlich-Instituts (PEI) veröffentlichte Übersicht zur dortigen vergleichenden Evaluierung der Sensitivität von SARS-CoV-2 Antigenschnelltests ab (siehe Webseite des PEI).

- „Ja" bedeutet, dass der Test bereits mit positivem Ergebnis durch das PEI evaluiert wurde.
- „Nein" bedeutet, dass bislang keine entsprechenden Testergebnisse vorliegen.

Im Falle einer negativen Evaluierung durch das PEI streicht das BfArM den entsprechenden CE-gekennzeichneten Test von seiner Liste. Für eine Sonderzulassung ist eine positive Evaluierung des PEI eine zwingende Voraussetzung.

Hinweis: Eine aktuelle Übersicht der SARS-CoV-2-Tests, die von den europäischen Mitgliedsstaaten gegenseitig für COVID-19-Testergebnisbescheinigungen anerkannt werden und damit für das „EU Digital COVID-19 Certificate" berücksichtigt werden können, finden Sie im entsprechenden Dokument der Europäischen Kommission: Link zum Dokument

ANHUI DEEPBLUE MEDICAL | Los | Aktionen | Zurücksetzen

Nach 'ANHUI DEEPBLUE MEDICAL' suchen

			Hersteller			Europäischer Bevollmächtigter				Sensitivität		Spezifität		
Test-ID	Handelsname	Evaluierung PEI	Name	Stadt	Land	Name	Stadt	Land	Testort*	%	95%iges Vertrauens-intervall	%	95%iges Vertrauens-intervall	Gebrauchsa...
AT031/20	Covid-19 (SARS-CoV-2) Antigen Test (Colloidal Gold)	Ja	Anhui Deepblue Medical Technology Co. Ltd.	Hefei, Anhui	CN	Luxus Lebenswelt GmbH	Willich	DE	POC (ohne Gerät)	96,40	90,8 - 98,2	99,80	94,4 - 99,9	Link...
AT535/21	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) - Savila	Nein	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,Ltd	Hefei	CN	Luxus Lebenswelt GmbH	Willich	DE	POC (ohne Gerät)	97,10	90,8 - 98,2	99,80	94,4 - 99,9	Link...
AT1231/21	COVID-19 (SARS-CoV-2) Antigen Test Midstream - Saliva	Nein	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	Hefei, China	CN	Luxus Lebenswelt GmbH	Willich	DE	POC (ohne Gerät)	97,50	90,9 - 99,2	99,50	94,9 - 99,9	Link...

1 Zeilen ausgewählt 1 - 3 von 3

Passed the PEI evaluation.

		Hersteller	
Name des Tests	Evaluieru... PEI	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

French ANSM Self test and Professional use test registration

MINISTÈRE
DES SOLIDARITÉS
ET DE LA SANTÉ
Liberté
Égalité
Fraternité

LISTE DE TESTS COVID-19

Cette liste de tests a été générée depuis la plateforme covid-19.sante.gouv.fr suite à un filtre appliqué aux tests présents sur la plateforme.

Nom du test	Sous-type de test	Fabricant	Distributeur	Marquage CE	Conformité HAS	Validation UE	Type de test	Cibles	Type de prélèvement
COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)	Antigénique non automatisé (dont TROD)	Anhui Deepblue Medical Technology		Oui	Oui	Oui	Antigénique		Nasopharyngé
COVID-19 (SARS-CoV-2) Antigen Test Kit	Autotest	ANHUI DEEPBLUE MEDICAL TECHNOLOGY		Oui	Oui	Non	Antigénique	N	Nasal

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **2145379**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:15/08/2021

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2145379	S	SL030101NST-1; SL030101NST-5	COVID-19 (SARS-COV-2) ANTIGEN TEST KIT (COLLOIDAL GOLD) - SELF-TEST	W0105040619 - CORONAVIRUS	ST - Test autodiagnostici (non inclusi nell'all. II)	06/08/2021		FABBRICANTE	ANHUI DEEP BLUE MEDICAL TECHNOLOGY CO.,LTD			CN
									MANDATARIO	LUXUS LEBENSWELT GMBH		DE305829099	DE

<< < Pagina:1 > >> Num. Pagine:1 Num. Dispositivi:1

Italy Self Test Registration