DEEPBLUE

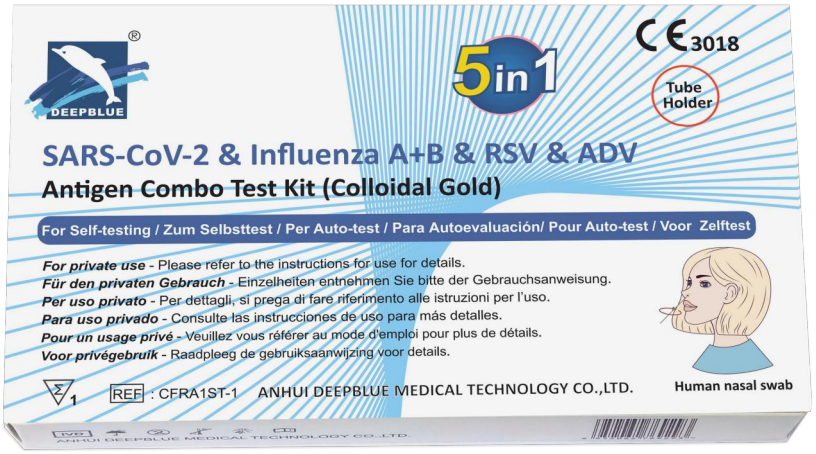
CE 3018

EU-IVDR

SARS-CoV-2 & Influenza A+B & RSV & ADV Antigen Combo Test Kit (colloidal Gold)

Self Testing

Anhui Deepblue Medical Technology Co.,Ltd.
Website: www.dbluemedical.com
Address: No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA



1pc/box, 400pcs/carton

Box size：130*65*19mm

Carton size: 54*40*35 cm Weight: 13.5 kg

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

Box size：130*75*55mm

Carton size: 57*54*40cm

15 pcs / box 50 boxes /carton --750 Tests /carton

Box size :260*120*70mm

Carton size: 62*54*38cm

Your kit contains the following materials

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

EU-IVDR

WWW.DBLUEMEDICAL.COM

DEEPBLUE

CE 3018

ISO 13485:2016 Medical Devices

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

SARS-CoV-2 & Influenza A+B & RSV & ADV Antigen Combo Test Kit (Colloidal Gold)

5in1 **SELF-TESTING!**

	SARS-CoV-2	Influenza A+B	RSV	ADV
Sensitivity	96.8%	> 99.9%	> 99.9%	99%
Specificity	> 99.9%	> 99.9%	> 99.9%	> 99.9%

Email:
sales@dbluemedical.com

Add:
No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui, China

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

Product Characteristics

- Specimen: Nasal Swab
- Storage: Store at 2-30 ℃
- Package:1/5/25 pcs / box
- Detection Time: 15 Minutes
- Shelf Life: 24 Months

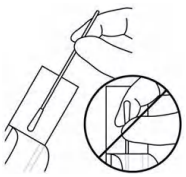
Features

※ High Accurate

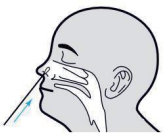
※ Easy To Operate at Home

※ Convenient : (5 in 1) Five infections detected in one test

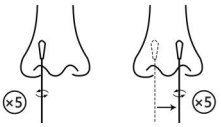
Test Procedure

① 

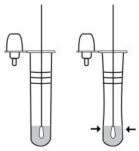
Remove the sterilized swab

② 

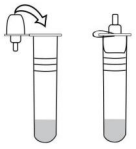
Carefully insert the swab into the your nostril, the swab tip should be inserted up to 2 cm until resistance is met

③ 

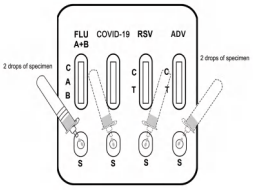
Roll the swab firmly around the inside of the nostril, making 5 complete circles. Using the same swab, repeat this process for the other nostril to ensure an adequate amount of specimen is collected

④ 

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

⑤ 

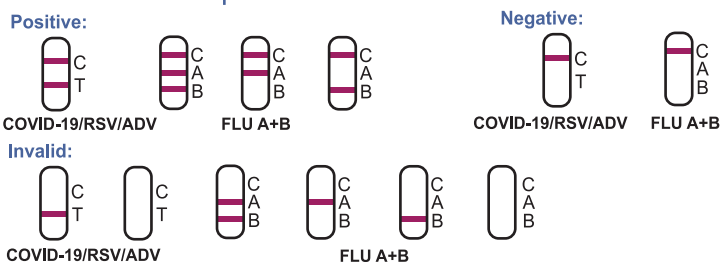
Press the nozzle cap firmly onto the extraction tube

⑥ 

Hold the Antigen extraction tube vertically and add two drops of the test specimens into each specimen well (S)

⑦ 

⑧ Interpretation of test results



Email:
sales@dbluemedical.com

Add:
No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui, China

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

DEEPBLUE

www.dbluemedical.com

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Anhui Deepblue Medical Technology Co., Ltd. No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000018785
European Representative:	Mega Eurostar Sp. z o. o. ul. Obrzeżna 5XIP/1, 02-691, Warsaw, Poland
SRN:	PL-AR-000042730
Product Name:	SARS-CoV-2 & Influenza A+B & RSV & ADV Antigen Combo Test Kit (Colloidal Gold)
Product Model:	Cassette
EMDN:	W0105099099
Basic UDI-DI:	69520627J034LD
Classification acc. to IVDR Ax. VIII:	Class C, rule 4 of IVDR Annex VIII
Conformity Assessment Procedure:	Pursuant to Regualtion (EU) 2017/746, Annex IX Chapters I, II and III
CE Certificate No.:	EU-TDA-FI-20642-800030-2025-1
Name and ID of the Notified Body:	Sertio Oy Notified Body 3018 Biokatu 10, 33520 Tampere Finland NB number: 3018 E-mail: info@sertio.fi

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

START OF CE-MARKING: March 21th, 2025

PLACE, DATE OF ISSUE: Anhui Hefei, China, March 28th, 2025

SIGNATURE:

CE 3018

EU Declaration of Conformity

SL-CE80-CFRA-8.1 (A/1)

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Manufacturer:	**ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.** No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui PEOPLE'S REPUBLIC OF CHINA
Single registration number:	CN-MF-000018785
Authorized representative:	**Mega Eurostar Sp. z o. o.** Obrzeżna, 5 lok. XIP/1 02-691 Warsaw Poland
Single registration number:	PL-AR-000042730

Notified Body Sertio Oy declares that the requirements of Annex IX, Chapter II of the

REGULATION (EU) 2017/746 on In Vitro Diagnostic Devices

have been met for the products listed in this certificate.
The above mentioned manufacturer has established and maintains a technical documentation defined by Annex IX chapter II. In addition to this certificate an EU Quality Management System certificate is required before placing the listed product on the market.

Certificate validity is subject to manufacturer fulfilling the obligations arising from the Annex IX of the aforementioned regulation. Validity of the certificate is subject to following the General terms of Business by Sertio Oy and Terms of conformity assessment of IVD medical devices.

Certificate number	EU-TDA-FI-20642-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

SERTIO SERTIO SERTIO SERTIO NOTIFIED BODY CE 3018

Mikko Soikkeli

Sertio Oy

Biokatu 10, 33520 Tampere, Finland

PRODUCTS

Certificate number	EU-TDA-FI-20642-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

Class C for self testing

IVR 0503	Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W0105099099	Virology – RT & POC - other
Product name:	SARS-CoV-2 & Influenza A+B & RSV& ADV Antigen Combo Test Kit(Colloidal Gold)
Model:	CFRA1ST-X
Basic-UDI-DI:	69520627J034LD
Intended use:	This product is used for the qualitative detection of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV) and adenovirus antigen in human nasal swab specimens. It is a non-automated rapid test method for infection. This test is authorized for non-prescription home use with self collected anterior nasal (nares) swab samples from individuals. Individuals who test positive should seek follow up care with their physician or healthcare provider as additional testing may be necessary. Users under the age of 15 should complete the test with supervision of an adult. Both symptomatic and asymptomatic infections can be tested.

Certificate history

Certificate number	EU-TDA-FI-20642-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

Version	Date issued	Description
1	21.03.2025	Initial certification

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Manufacturer:	**ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.** No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui PEOPLE'S REPUBLIC OF CHINA
Single registration number:	CN-MF-000018785
Authorized representative:	**Mega Eurostar Sp. z o. o.** Obrzeżna, 5 lok. XIP/1 02-691 Warsaw Poland
Single registration number:	PL-AR-000042730

Notified Body Sertio Oy declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the

REGULATION (EU) 2017/746
on In Vitro Diagnostic Devices

have been met for the products listed in this certificate.
The above mentioned manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation.

Certificate validity is subject to manufacturer fulfilling the obligations arising from the Annex IX of the aforementioned regulation. Validity of the certificate is subject to following the General terms of Business by Sertio Oy and Terms of conformity assessment of IVD medical devices.
NOTE: For class A sterile devices: "Audit by the notified body was limited to the aspects of manufacture concerned with securing and maintaining sterile conditions".

For placing in the market class D devices, companion diagnostic devices, devices for self testing and devices for near patient testing, in addition to this certificate a separate EU technical documentation assessment certificate according to Annex IX chapter II is required and has been issued with certificate number: EU-TDA-FI-20642-800030-2025-1

Certificate number	EU-QMS-FI-44290-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

Mikko Soikkeli
Sertio Oy
Biokatu 10, 33520 Tampere, Finland

PRODUCTS

Certificate number	EU-QMS-FI-44290-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

Class C for self testing

IVR 0503	Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
IVP 3007	Immunoassays
W0105	Infectious diseases

Certificate history

Certificate number	EU-QMS-FI-44290-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

Version	Date issued	Description
1	21.03.2025	Initial certification

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. 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

TÜV SÜD 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:

TÜV SÜD ISO 13485

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

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

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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

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QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00124Q39419R1M/3400

We hereby certify that

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.

Business Registration Number: 913401005501903714

No.777, Jimingshan Road, High-Tech Development Zone, Hefei, Anhui, PEOPLE′S REPUBLIC OF CHINA

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

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 and Virus Sampling Tube within the Scope of Qualification′s Development and Production

Certified since: November 11, 2021 Valid from: October 31, 2024 Valid until: November 10, 2027

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

MEMBER OF IQNET

中国质量认证中心
CHINA QUALITY CERTIFICATION CENTRE

Section 9, No. 188, Nansihuan Xilu, Beijing 100070 P. R. China http://www.cqc.com.cn

2024年版

EN
No.IFU-CFRA-NST-01,Ver.A/7

CE 3018

SARS-CoV-2 & Influenza A+B & RSV & ADV Antigen Combo Test Kit (Colloidal Gold)

For in vitro diagnostic use only. For self-testing.
Please read the instruction carefully before use.

Operational Use Video

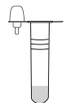
[Intended use]

This product is used for the qualitative detection of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV) and adenovirus antigen in human nasal swab specimens. It is a non-automated rapid test method for infection. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals. Individuals who test positive should seek follow up care with their physician or healthcare provider as additional testing may be necessary. Users under the age of 15 should complete the test with supervision of an adult. Both symptomatic and asymptomatic infections can be tested.

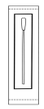
[Materials and Components]

Test Device


Instruction


Antigen Extraction Tube with Extraction Reagent

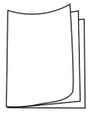

Collection Bag


Sterilized Swab


Timer (Materials required but not provided)

[Preparation before the test]


Blow your noses several times before taking the specimen. Clean your hands, make sure they are dry before starting the test.


Read the instructions Carefully.

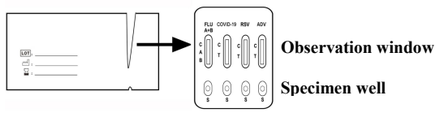

Check all parts of the test kit to make sure that all parts are complete and not damaged.


Check the Expiration Date printed on the foil pouch of the test device.

[Test Procedure]

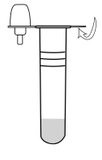
Allow test device extraction reagent and specimens to equilibrate to room temperature (15～30 ℃） prior to testing.
Please keep the temperature at 15～30 ℃ and the humidity at 20%-80% during the whole test.

1.

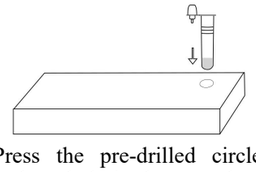


Open the package and take out the test device. Know the observation window and specimen well(S). It should be used within one hour.

2.


Gently peel off the aluminium foil seal.

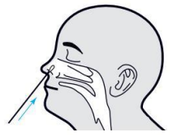
3.


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.

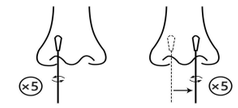
4.


Remove the sterilized swab from the packaging.

5.

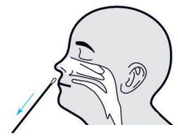

Relax your head naturally. Carefully insert the swab into the your nostril, the swab tip should be inserted up to 2 cm until resistance is met.

6.

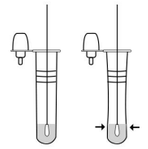


Roll the swab firmly around the inside of the nostril, making 5 complete circles. Using the same swab, repeat this process for the other nostril to ensure an adequate amount of specimen is collected.

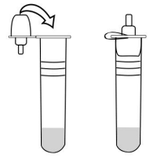
7.


Withdraw the swab from the nasal cavity.

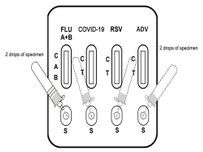
8.


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.

9.


Press the nozzle cap firmly onto the extraction tube.

10.



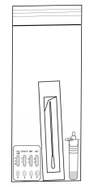
Hold the Antigen extraction tube vertically and add two drops of the test specimens into each specimen well(S).

11.


15 min

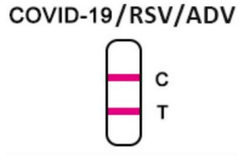
Read result at 15 minutes.
Do not read results after 30 minutes.

12.

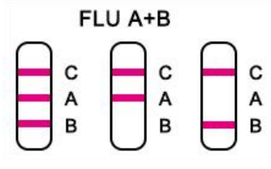

Please put all used materials in the enclosed collection bag for proper disposal. The test kit can be disposed of with normal household waste in compliance with the applicable local regulations.

[Interpretation of test results]

Positive result:



For COVID-19/RSV/ADV:
If both the control line (C) and the test line (T) appear, it indicates that SARS-CoV-2/RSV/ADV antigen has been detected and the result is positive.



For Flu A+B:

- If the quality control line C and the test line A&B all appear, indicating that influenza A&B antigens have been detected and the result is positive.
- If both the quality control line C and the test line A appear, indicating that influenza A antigen has been detected and the result is positive.
- If both the quality control line C and the test line B appear, indicating that influenza B antigen has been detected and the result is positive.

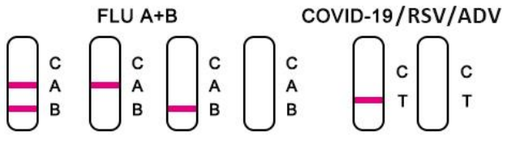
Note: The test line (T) could show different shades of color. However, even a very weak test line should be judged as a positive result during the specified observation period, regardless of the color of the test line.

Negative result:

FLU A+B COVID-19/RSV/ADV

If only quality control line C appear, test line T or test line A or test line B are colorless, it means that no antigen of corresponding pathogen is detected, and the result is negative.

Invalid result:



If the quality control line C is not observed, it will be invalid regardless of whether there is test line T or test line A or test line B, and the test shall be conducted again.

[Summary]

COVID-19

The novel corona viruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel corona virus 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. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. Once infected with the SARS-CoV-2 virus, you may be hospitalized and some complications may occur.

Influenza

Influenza, usually called "flu", is an acute respiratory infectious disease caused by influenza viruses. It is highly contagious and is spread mainly through coughing and sneezing. It usually breaks out in spring and winter. Divided into influenza A virus, influenza B virus and influenza C virus. Influenza A virus has strong variability, followed by influenza B virus, and influenza C virus is very stable, so influenza A virus is more serious and prevalent than influenza B virus.

Respiratory syncytial virus (RSV)

Respiratory syncytial virus is a common, and very contagious, virus that infects the respiratory tract of most children before their second birthday. In children hospitalized with RSV infection, it is believed to be the most common viral cause of death in children younger than 5 years, particularly in children younger than one year. RSV infection can cause cold-like symptoms, including a cough and runny nose, which usually last 1 to 2 weeks. Respiratory syncytial virus spreads through the air, like after a cough or a sneeze, and through direct contact like touching.

Adenovirus (ADV)

Symptoms of respiratory illness caused by Adenovirus infection range from the common cold syndrome to pneumonia, croup and bronchitis. Patients with compromised immune systems are especially susceptible to severe complications of Adenovirus infection. Adenovirus is transmitted by direct contact, fecal-oral transmission and occasionally waterborne transmission. Some types are capable of establishing persistent asymptomatic infections in tonsils, adenoids and intestines of infected hosts and shedding can occur for months or years.

The gold standard method for laboratory diagnosis is the virus isolation and culture method, while the long cycle time for cell culture identification seriously affects the timely clinical guidance of patient medication, and the method is limited in clinical application. Compared with the cell culture method, reverse transcription-polymerase chain reaction (RT-PCR) has higher sensitivity, but the cost of RT-PCR method is higher, the experiment time takes 4-6 hours, and the experiment operation is more professional, so the field application is restricted. This product uses the rapid self test method and is suitable for the auxiliary diagnosis of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV) and adenovirus.

[Test principle]

This kit uses the double antibody-sandwich method to detect antigens. When an appropriate amount of specimen is added to the specimen well(s) of the test device, the specimen will move forward along the test device. If the specimen contains an antigen, the antigen binds to the antibody labeled with colloidal gold on the binding pad, and the immune complex forms a sandwich complex with another coated antibody which was coated on the test line, a visible colored line will show up, which indicates that the antigen is positive. The test device also contains a quality control line, regardless of whether there is a test line, the red quality control line should appear. If the quality control line does not appear, it indicates that the test result is invalid and you need to do the test again.

[Limitations of inspection methods]

1. This product is used for qualitative testing only and cannot indicate the level of antigen in the specimen.
2. This test kit is only used to detect human nasal swab specimens. The results of other specimens may be wrong.
3. Negative results may occur if the antigen titre in the specimen falls below the minimum detection limit of this kit.
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. Diagnosis and treatment can not only rely on this test result. Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.
6. 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 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. 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.

[Warnings and Precautions]

1. For *in vitro* diagnostic use.
2. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you may get inaccurate results.
3. Guard against moisture, do not open the aluminum foil bag before it is ready for testing. Do not use it if the aluminum foil bag or label of sterilized swab is damaged or the test device is damp.
4. Please use it within the validity period.
5. Balance all reagents and specimens to room temperature (15 ~ 30 ℃) before use.
6. Do not replace the components in this kit with components from other kits.
7. Do not dilute the specimen when testing, otherwise you may get inaccurate results.
8. The kit shall be stored in strict accordance with the conditions specified in this Instruction. Please do not store the kit under freezing conditions.
9. The test methods and results must be interpreted in strict accordance with this specification.
10. The extraction reagent is individually packed, the batch number, expiration date and other information cannot be marked separately as the space is limited, but this information will be consistent with the corresponding test kit.
11. Any serious incident occurring during the use of the equipment should be reported to the manufacturer and to the competent authorities of the Member State in which the user and/or the patient is based.

[Storage conditions & period of validity]

1. The kit should be stored at 2-30 ℃ until the expiry date printed on the sealed pouch.
2. After the foil pouch is unsealed, the test device should be used as soon as possible within one hour.
3. The test device should be kept away from direct sunlight, moisture and heat.
4. Do not freeze the test kit.

[Sample Transport and Storage]

Freshly collected specimens should be processed as soon as possible. It should be no later than one hour after collection. The processed specimens could be stored at 2-8℃ for no more than 24 hours.

[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. Physical characters

1.1. Appearance

The test should be clean and complete, no burr, no damage and non-pollution. The shell of the test cassette should be flat, the upper and lower covers should be evenly closed, and there should be no obvious gap. The inner test strip should be firmly attached without

waggle. The extraction reagent (50 mM Tris + 150 mM NaCl + 0.1% $C_{12}H_{25}SO_4Na$ + Tween 20) should be free of foreign matter.

1.2. Size: The size of the inner strip should not be less than 2.5mm.

1.3. Liquid migration speed: It should not be less than 10mm/min.

2. Limit of detection (LOD)

Type		LOD
COVID-19		80 $TCID_{50}$/ml
Influenza A	Liao Ning/1183/2007 (H1N1)	2.2×10^3 $TCID_{50}$/mL
Influenza A	A/Victoria/3/75	1.16×10^2 $TCID_{50}$/mL
Influenza A	A/HongKong/8/68	2.58×10^4 $TCID_{50}$/mL
Influenza B	Jiang Xi/32/2000	2.9×10^2 $TCID_{50}$/mL
Influenza B	B/1704	6.8×10^2 $TCID_{50}$/mL
RSV		10 ng/ml
ADV		10 ng/ml

3. Cross reaction:

3.1. For COVID-19:Potentially cross-reacting specimens ≥50 in total,

Cross reacting specialties include Adenovirus 3, Parainfluenza virus Type 2, Human coronavirus NL63, MERS, coronavirus (Pseudovirus, part of ORFlab+N gene), Human coronavirus 229E, Human coronavirus OC43, Human Coronavirus HKU1, SARS-COV-2, Pseudovirus (N full-length gene), 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, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Pneumocystis jirovecii, Pseudomonas Aeruginosa, Human Metapneumovirus (hMPV), Parainfluenza virus Type 1, Staphylococcus Epidermidis, Streptococcus Salivarius, etc.

3.2. For Flu A+B:

Influenza A virus and influenza B virus do not cross each other.

Do not cross react with influenza C virus, parainfluenza virus, adenovirus, respiratory syncytial virus, herpes simplex virus, mumps virus, rhinovirus, respiratory chlamydia, mycoplasma, tuberculosis, bacillus pertussis, candida albicans, diphtheria, influenza Haemophilus, Legionella pneumophila, Mycobacterium tuberculosis, Staphylococcus aureus, gastrointestinal virus 71, coronavirus, etc.

3.3. For RSV and ADV:

Do not cross react with SARS-CoV-2, Influenza A, Influenza B, etc.

4. Interfering substances

4.1. For COVID-19:

There is no interference with test results, such as Parainfluenza virus Type 1, Parainfluenza virus Type 2, Parainfluenza virus Type 3, Parainfluenza virus Type 4a, Adenovirus (e.g. C1 Ad. 71), Human Metapneumovirus (hMPV), Influenza A H3N2 (Wisconsin/67/05), Influenza A H1N1, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Influenza B (Malaysia/2506/04), Enterovirus, Respiratory syncytial virus, Rhinovirus, Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Pneumocystis jirovecii, Pseudomonas Aeruginosa, Candida albicans, Pooled human nasal wash, Bordetella pertussis, Mycoplasma pneumoniae, Staphylococcus Epidermidis, Streptococcus Salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS coronavirus, etc.

4.2. For Flu A+B, RSV and ADV:

Common interfering substances in the sample, such as blood, mucin, pus, etc., have no effect on the test results.

5. Clinical performance

5.1. For COVID-19:

A total of 630 samples were collected in this study. Among them, 420 samples (220 positive and 200 negative) were used for professional testing, and 210 samples were used for usability studies (30 positive and 180 negative). Therefore, there were a total of 250 positive samples and 380 negative samples in this study.The statistical data of clinical research results are shown in the following table:

Reference RT-PCR analysis							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	96.80%	94.62%	98.98%
	POS	242	0	242	NPA	＞99.9%	99.03%	100%
	NEG	8	380	388	Total compliance rate			98.73%
	TOTAL	250	380	630				

Specificity:＞99.9%; Sensitivity: 96.80%; Accuracy: 98.73%

5.2. For Flu A:

A total of 305 samples were collected in this study, of which 105 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Control reagent							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	＞99.9%	96.47%	100%
	POS	105	0	105	NPA	＞99.9%	98.12%	100%
	NEG	0	200	200	Total compliance rate			＞99.9%
	TOTAL	105	200	305				

Specificity: >99.9%; Sensitivity: >99.9%; Accuracy: >99.9%

5.3. For Flu B:

A total of 305 samples were collected in this study, of which 100 were positive and 205 were negative. The statistics of the study results are shown in the following table:

Control reagent							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	＞99.9%	96.30%	100%
	POS	100	0	100	NPA	＞99.9%	98.16%	100%
	NEG	0	205	205	Total compliance rate			＞99.9%
	TOTAL	100	205	305				

Specificity: >99.9%; Sensitivity: >99.9%; Accuracy: >99.9%

5.4. For RSV:

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Control reagent							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	＞99.9%	96.30%	100%
	POS	100	0	100	NPA	＞99.9%	98.12%	100%
	NEG	0	200	200	Total compliance rate			＞99.9%
	TOTAL	100	200	300				

Specificity: >99.9%; Sensitivity: >99.9%; Accuracy: >99.9%

5.5. For ADV:

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Control reagent							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE		POS	NEG	Total	PPA	99.00%	94.55%	99.82%
	POS	99	0	99	NPA	＞99.9%	98.12%	100%
	NEG	1	200	201	Total compliance rate			99.67%
	TOTAL	100	200	300				

Specificity: ＞99.9%; Sensitivity: 99.00%; Accuracy: 99.67%

[Index of Symbols]

IVD	In vitro diagnostic *medical device*		Do not re-use		Keep away from sunlight
	Use-by date		Consult instructions for use or consult electronic instructions for use		Date of manufacture
	Caution		Manufacturer		Do not use if package is damaged and consult instructions for use
30℃ 2℃	Temperature limit	LOT	Batch code	Σ	Contains sufficient for <*n*> tests
EC REP	Authorized representative in the European Community/ European Union		Keep dry	CE 3018	CE Mark

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E-mail:sales@dbluemedical.com

EC REP Mega Eurostar Sp. z o. o.
ul. Obrzeżna 5XIP/1, 02-691, Warsaw, Poland

Specification	REF
1 piece per box	CFRA1ST-1
2 pieces per box	CFRA1ST-2
3 pieces per box	CFRA1ST-3
5 pieces per box	CFRA1ST-5
10 pieces per box	CFRA1ST-10
15 pieces per box	CFRA1ST-15
20 pieces per box	CFRA1ST-20
25 pieces per box	CFRA1ST-25

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