MEDOMICS MEDICAL TECHNOLOGY Co., Ltd.
Tel / +86 (0)25-58601060 • Web / www.medomics-dx.net • E-mail / overseas@medomics-dx.com
ADD / F3, BuildingC, No.3-1XinjinhuRoad, Jiangbei New Area, Nanjing, China

SCAN ME

SARS-CoV-2 & Influenza A/B

Antigen Combo
Rapid Test Kit (LFIA)

Self-Testing

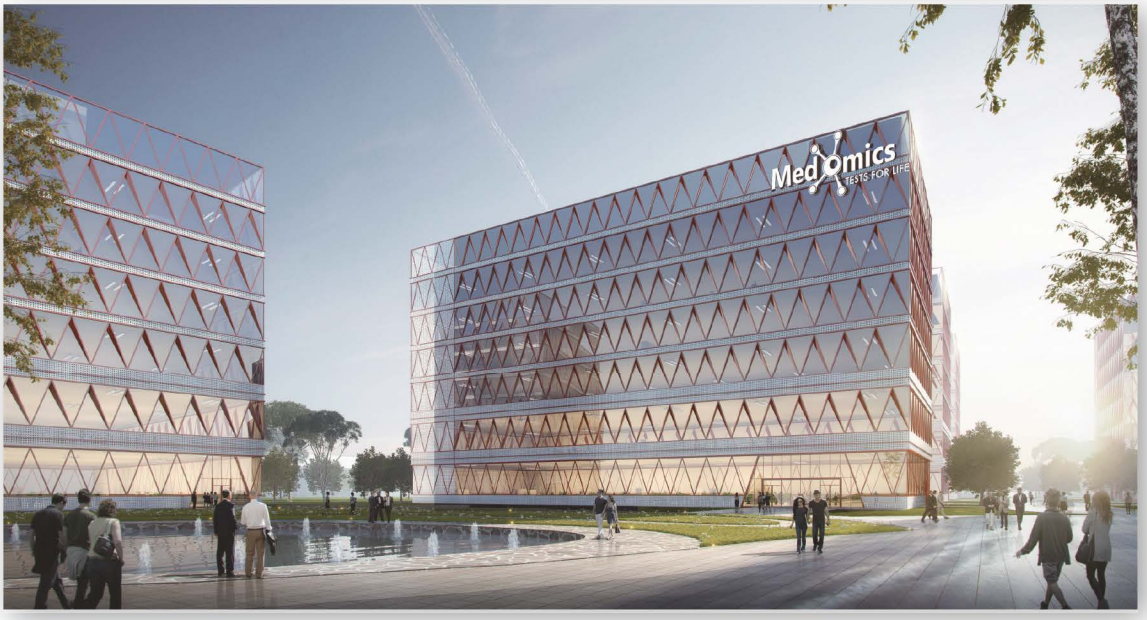
INFECTIOUS DISEASE

Company Profile

Jiangsu Medomics Medical Technology Co., Ltd., founded in October 2017, is located at Biotech and Pharmaceutical Valley of Jiangbei New Area, Nanjing, Jiangsu, China. We are an innovation-driven international high-tech enterprise, mainly engaged in R&D, production and sales of in vitro diagnostic reagents and supporting automated instruments.

Medomics focuses on the accurate detection in fields of infectious diseases, cardiovascular, infection, tumor, gynecology, etc. and has multiple technology platforms, including but not limited to the fluorescent staining technology, protein labeling technology, time-resolved immunofluorescence detection technology, molecular biology, artificial intelligence image processing and analysis technology. Medomics also possesses GMP purification production workshops that meet FDA, IVDR, and NMPA standards.

At the beginning of the coronavirus epidemic, Medomics Medical developed SARS-CoV-2 neutralizing antibody test kit, and published the world's first related paper in an international journal. Medomics' Covid-19 test kits have achieved certificate of CE, TGA, BfArM, TUV, etc. And have been exported to more than 60 countries.



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Intended Use

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2, Influenza A and Influenza B virus antigen in anterior nasal swabs from individuals suspected of COVID-19, Influenza A and Influenza B within the first seven days of symptom onset. SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) shall not be used as sole basis to diagnose or exclude SARS-CoV-2, Influenza A and Influenza B infection.

Three in one
one step process differentiate 3 infections

Rapid
Results in 15 minutes

Effective for mutation viruses
Delta, Omicron, etc.

Easy process
self operation, no extra equipment needed

Easy storage
room temperature storage and transportation

Single strip design
one strip design with one time sample addition, not two or three parallel strips in one cassette

Specification	Packaging	Box dimension	Box qty/ctn	Kit qty/ctn	Carton Dimension	Gross weight/ctn (kg)	CBM
1041-14-01	1Kit/ Box	165*45*20	572	572	500*350*600	18.3	0.105
1041-24-01	2Kits/ Box	165*45*30	360	720	500*350*600	14.5	0.105
1041-34-01	5Kits/ Box	165*45*60	192	960	500*350*600	15.2	0.105
1041-54-01	20Kits/ Box	165*95*95	60	1200	500*350*600	14.5	0.105

Packing size:
1 pc/Box/ 2 pcs/Box
5 pcs/Box/ 20 pcs/Box
50 pcs/Box/ 100 pcs/Box

Storage:
2-30℃

Detection Time:
15-20minutes

Shelf Life:
24 months

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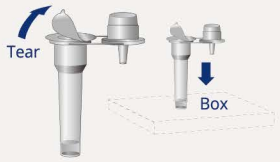
operation process

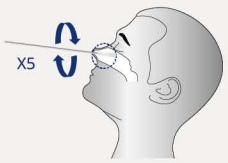
1

Tear the seal of the lysis buffer and place it on the test-tube rack



2

Use the swab to collect an anterior nasal sample



3

Rotate the swab against the inner tube wall 10 times, squeeze the swab from the outer tube wall 5 times to completely dissolve the sample in the buffer

Remove and discard the swab, cover the tube with the dropper

4

Add 4 drops (approximately 100 μL) processed sample extract into the sample well

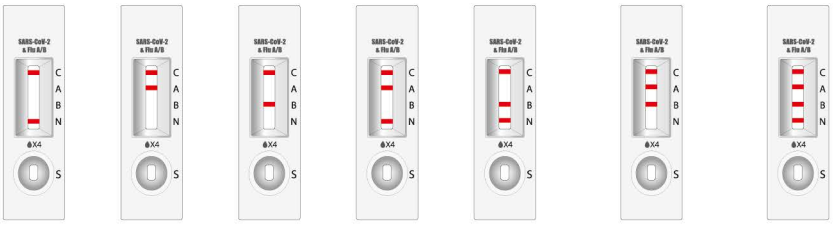
5

Observe the result within 15-20 minutes

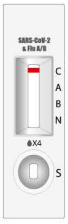
6

DISPLAY OF THE RESULT / EXPECTED VALUES

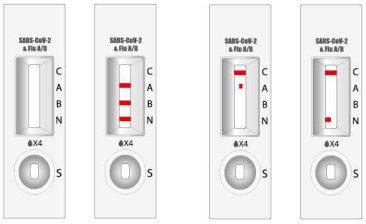
Positive +



Negative -



Invalid ×



Read the results within 15-20 minutes.

QUALIFICATIONS

CERTIFICATE

EC Certificate No. 1434-IVDD-193/2022
EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Jiangsu Medomics Medical Technology Co., Ltd.
F3, Building C, No.3-1 Xinjinhu Road,
Jiangbei New Area, Nanjing, Jiangsu 210030 CHINA

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)
Ref. no.: 1041-14-01, 1041-24-01, 1041-34-01, 1041-54-01

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 24.05.2022 to 27.05.2025

The date of issue of the Certificate: 24.05.2022

The date of the first issue of the Certificate: 24.05.2022

CE 1434

Issued under the Contract No. MD-206/2021
Application No: 582/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2022
Module A1

Elektronicznie podpisany
przez Tomasz Artur Koeber
Data: 2022.05.24 07:10:38
+02'00'

Director
Medical Device Certification
Department

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