Medomics
TESTS FOR LIFE

INFECTIOUS DISEASE

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)

Company Profile

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)

MEDOMICS

Jiangsu Medomics Medical Technology Co., Ltd., founded in October 2017, is located at Biotech and Pharmaceutical Valley of Jiangbei New Area, Nanjing, Jiangsu Province. It is an international high-tech enterprise driven by innovation in the area of medical devices R&D, production and sales. Medomics focuses on diagnosis of microorganisms, tumors and some rare diseases, mainly engaged in the research and development, production and sales of in vitro diagnostic reagents and automatic instruments.

At the very beginning of **COVID-19** on early 2020, **Medomics** developed IgM/IgG antibody detecting kit with the team of Zhong Nanshan. And Medomics published the first research paper on international journal together with State Key Laboratory of Respiratory Disease (National Clinical Research Center for Respiratory Disease, Guangzhou Institute of Respiratory Health). The detecting kit was validated by CDC, Harvard Medical School and Columbia University Irving Medical Center etc. The kit has been exported to dozens of countries and areas, making great help against SARS-CoV-2. At present, Medomics's series product of SARS-CoV-2 detection have been developed according to ISO 13485 Quality system and European CE Certification.

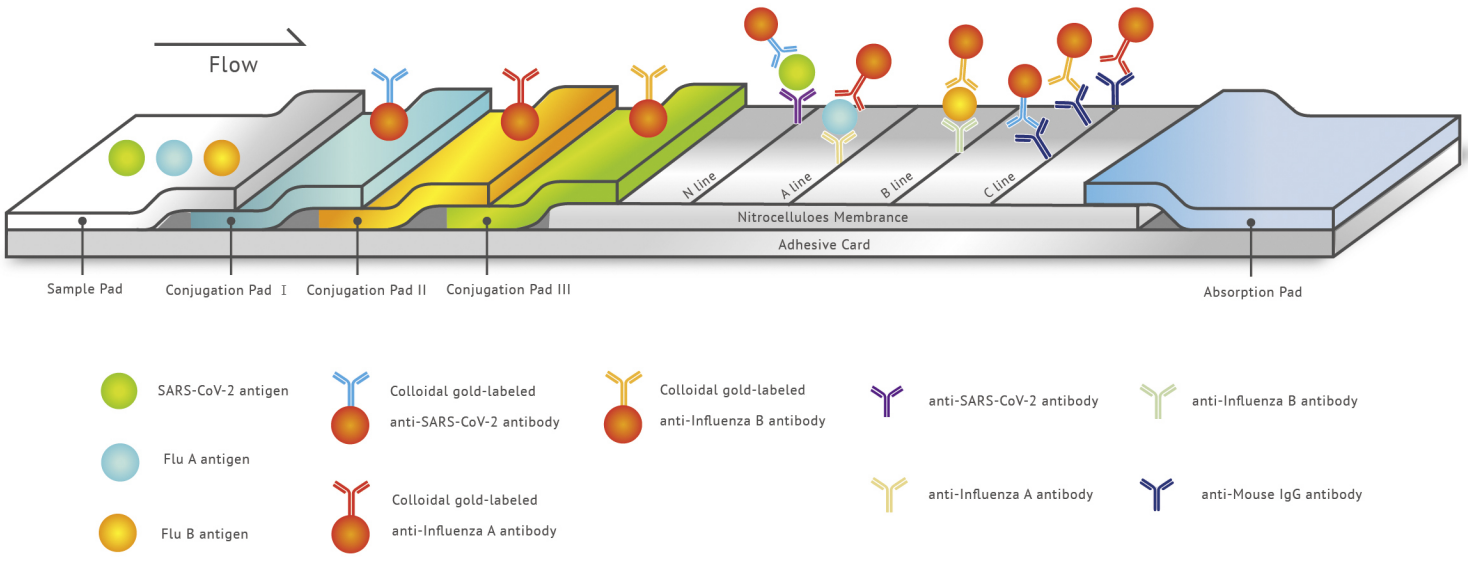
Test Principle

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)

Medomics SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) uses a double antibody sandwich method to detect SARS-CoV-2 and Influenza A/B by colloidal gold immunochromatography.

When the appropriate amount of test samples treated with lysis buffer is added to the sample well of the test cassatte, the sample will move forward along the test strip by capillary action. If the sample contains SARS-CoV-2 or Influenze A/B virus nucleocapsid antigen, and the concentration is higher than the limit of detection,the antigen will form immune complexes with corresponding Nucleocapsid Protein antibody labeled with colloidal gold respectively, which are captured by lines N line, A line, or B line. If test sample contains SARS-CoV-2 virus, forming a red N line, indicating a positive result for SARS-CoV-2. If test sample contains Influenza A virus, forming a red A line, indicating a positive result for Influenza A. If test sample contains Influenza B virus, forming a red B line, indicating a positive result for Influenza B.

Additionally, the test strip also contains a quality control line(C line). The C line should be formed to indicate that the sample has been transported properly through the membrane regardless of whether sample contains antigens or not. If the C line does not appear, it indicates that the test result is invalid and the sample need to retest.



Introduction of products

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)

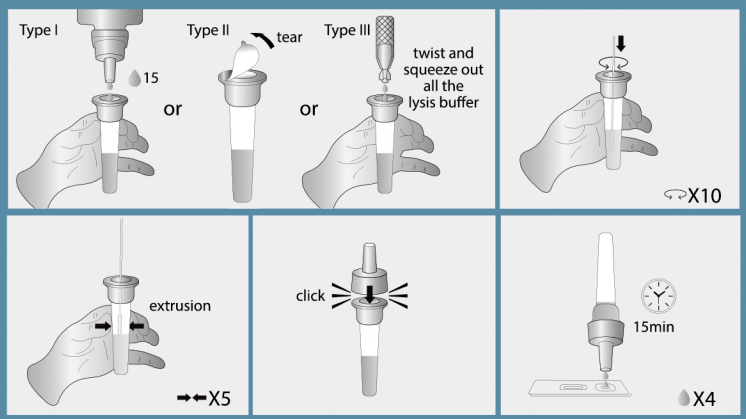
Packing size:
1 pc/box 、 5 pcs/box、
20 pcs/box 、 50 pcs/box 、
100 pcs/box

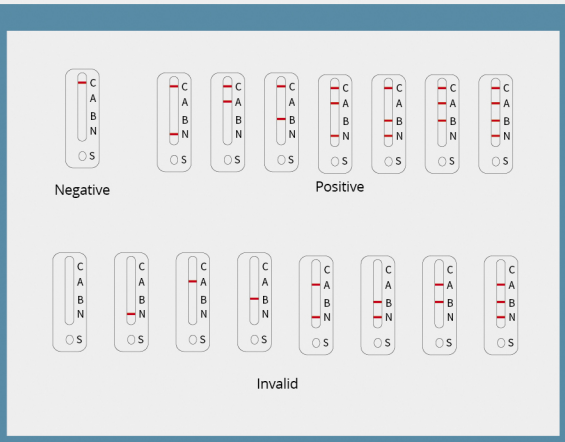
Specimen type:
Nasal swabs

Detection Time:
15-20minutes

Storage:
2-30°C

Shelf Life:
24 months





- Direct Detection Virus
- Easy Operation Fast
- High Sensitivity and Specificity
- No instruments Required
- Effectively distinguish SARA-CoV-2, Influenza A/B infections

Clinical Performance

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)

SARS-CoV-2 Test

Manufacturer/ Company	LoD	Positive Percentage
BD	140 $TCID_{50}$/mL	95%（19/20）
Abbott	22.5 $TCID_{50}$/Swab	100%（20/20）
Lumiradx	32 $TCID_{50}$/mL	100%（20/20）
Medomics	10 $TCID_{50}$/mL	100%（20/20）

Sensitivity and Specificity

The Medomcis SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) was evaluatedwith different clinical samples whose status were confirmed by RT-PCR. The results are shown in following tables. with different clinical samples whose status were confirmed by RT-PCR. The results are shown in following tables.

Anterior Nasal Anterior test

	RT-PCR		
Medomics SARS-CoV-2 Ag Test	**Positive**	**Negative**	**Total**
Positive	**107**	**1**	**108**
Negative	**5**	**103**	**108**
Total	**112**	**104**	**216**

Sensitivity: 95.54% (89.89%-98.53%)
Specificity: 99.04% (94.76%-99.98%)
Accuracy: 97.22% (94.05%-98.97%)

Positive predictive value: 99.07% (94.95%-99.98%)
Negative predictive value: 95.37% (89.53%-98.48%)

Influenza A/B Test

Wild type Virus Strain	LOD ($TCID_{50}$/mL)
A/Brisbane/02/2018(H1N1)	104
A/PUERTO/8/1934(H1N1)	102
A/Kansas/14/2017(H3N2)	102
A/Aichi/2/1968(H3N2)	102
A/Anhui/1/2013 (H7N9)	104
B/Colorado/06/2017(Victoria)	100
B/Phuket/3073/2013(Yamagata)	102
B/Chaoyang Beijing/12977/2017(Yamagata)	104

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