

**SARS-CoV-2  
Antigen Test Kit  
(LFIA)**



# Company Profile

**SARS-CoV-2  
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(LFIA)**

# MEDOMICS

**Jiangsu Medomics Medical Technology Co., Ltd.**, founded in October 2017, is located at Biotech and Pharmaceutical Valley of the National 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.





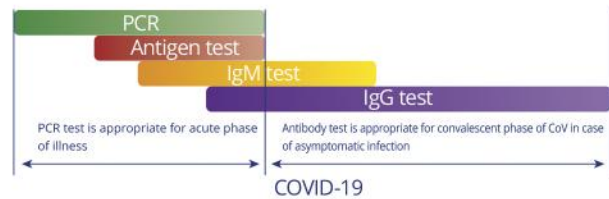
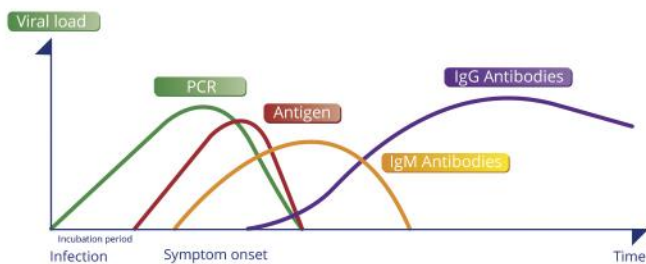
# Testing Methods for SARS-CoV-2

## SARS-CoV-2 Antigen Test Kit (LFIA)

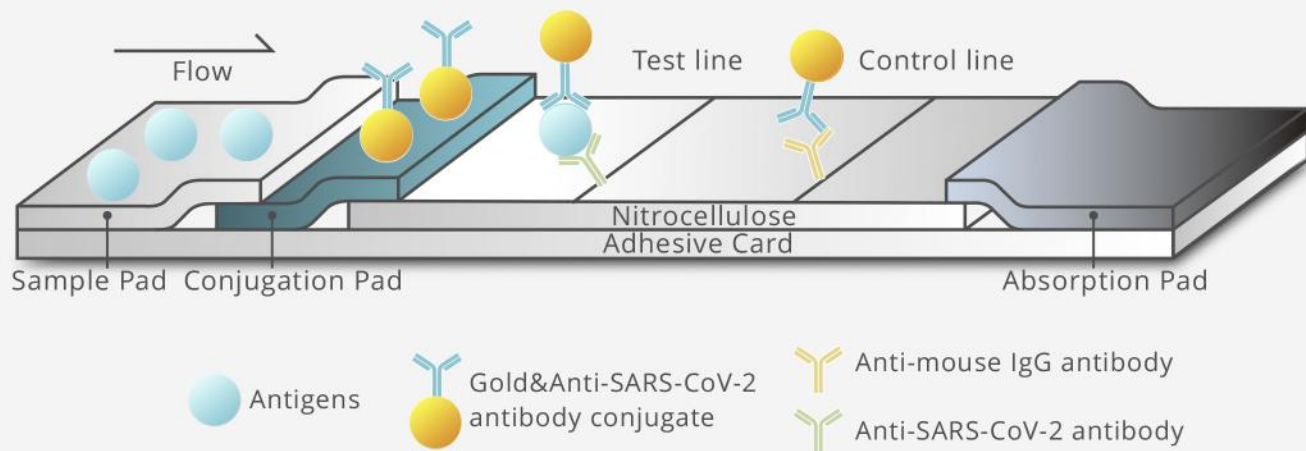
### SARS-CoV-2 Antigen Test Kit (LFIA)

Nasopharyngeal Swab  
Throat Swab  
Nasal Swab

Determine the infection of someone by detecting viral material.



## Test design and principle



- ▶ Colloidal gold-labeled anti-SARS-CoV-2 antibody is sprayed on conjugation pad.
- ▶ Test line is fixed with anti-SARS-CoV-2 antibody for detecting the novel coronavirus. The quality control antibody is fixed on the Control line.



# Clinical Performance

## SARS-CoV-2 Antigen Test Kit (LFIA)

### Sensitivity and Specificity

The Medomcis SARS-CoV-2 Antigen Test Kit (LFIA) was evaluated with different clinical samples whose status were confirmed by RT-PCR.

#### 1. Nasopharyngeal or throat secretion collection.

Sensitivity: 97.73%

Specificity: 100%

#### 2. Anterior Nasal secretion collection.

Sensitivity: 91.82%

Specificity: 100%



### Limit of Detection (LoD) Study Results

| Concentration TCID <sub>50</sub> /mL | Number Positive/Total | % Detected |
|--------------------------------------|-----------------------|------------|
| 10                                   | 20/20                 | 100%       |

| Manufacturer/ Company | LoD                           | Positive Percentage |
|-----------------------|-------------------------------|---------------------|
| BD                    | 140 TCID <sub>50</sub> /mL    | 95% (19/20)         |
| Abbott                | 22.5 TCID <sub>50</sub> /Swab | 100% (20/20)        |
| Lumiradx              | 32 TCID <sub>50</sub> /mL     | 100% (20/20)        |
| Medomcis              | 10 TCID <sub>50</sub> /mL     | 100% (20/20)        |



Rapid detection of novel coronavirus in 15 minutes



More obtainable specimen by nasal swab



Antigen detection is the better tool for rapid tracking of novel coronavirus infection



Suitable for monitoring novel coronavirus pneumonia



# Product introduction

## SARS-CoV-2 Antigen Test Kit (LFIA)



Packing size:  
20 tests/kit  
1 test/kit



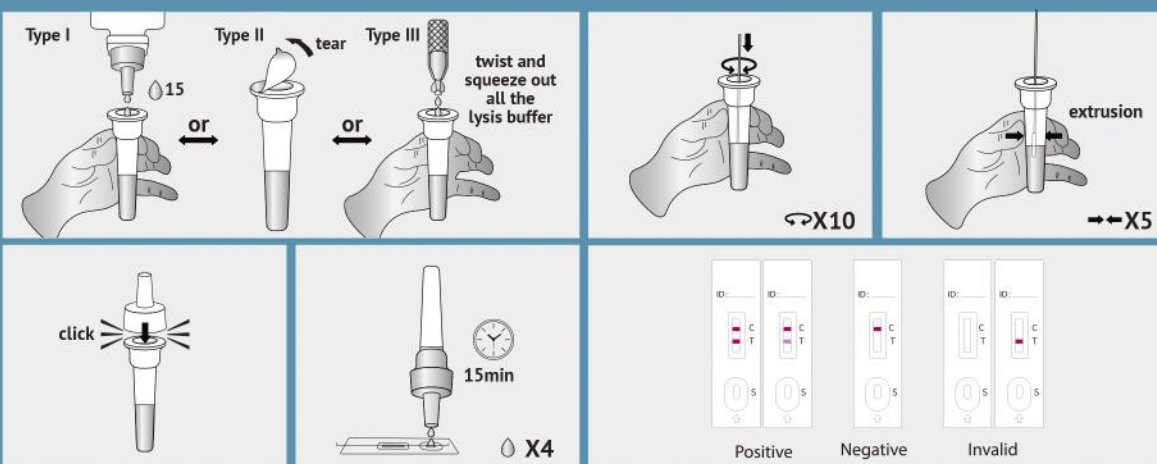
Specimen type:  
Nasopharyngeal swabs  
Throat swabs  
Nasal swabs



Storage:  
2-30°C



Shelf Life:  
24 months



Direct Detection of virus



Easy & Fast operation



High Sensitivity and  
Specificity



No instruments  
Required





# CERTIFICATE

**EC Certificate No. 1434-IVDD-481/2021**

**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 Xinjinhuroad, Jiangbei new  
area, Nanjing, Jiangsu, China**

in vitro diagnostic medical devices  
for self-testing

**SARS-CoV-2 Antigen Test Kit (LFIA)**

**REF: 1031-14-01, 1031-34-01, 1031-54-01**

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 03.11.2021 to 27.05.2024

The date of issue of the Certificate: 03.11.2021

The date of the first issue of the Certificate: 03.11.2021



Issued under the Contract No. **MD-82/2021**  
Application No: **547/2021**  
Certificate bears the qualified signature.  
Warsaw, 03/11/2021  
Module **A1**

Anna  
Małgorzata  
Wyroba  
Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.11.03  
15:03:24 +01'00'  
**Vice-President**  
*Mgr. Anna Wyroba*



# Packing info



| SARS-CoV-2 antigen Test Kit(LFIA) | Carton specifications | Quantity   | Carton dimension | Gross weight in carton | Carton volume |
|-----------------------------------|-----------------------|------------|------------------|------------------------|---------------|
| 1tests/kit                        | 400kits/carton        | 400 tests  | 64*42*51cm       | 13.9kg                 | 0.137m3       |
| 5tests/kit                        | 160kits/carton        | 800 tests  | 64*42*51cm       | 15.42kg                | 0.137m3       |
| 20tests/kit                       | 50kits/carton         | 1000 tests | 64*42*51cm       | 15kg                   | 0.137m3       |





## Medomics

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🌐 T e l / (+86) 25-58601213

📞 W e b / [www.medomics-dx.com](http://www.medomics-dx.com)

✉ E-mail / [overseas@medomics-dx.com](mailto:overseas@medomics-dx.com)

📍 A D D / F3,BuildingC,No.3-1XinjinhuaRoad,Jiangbei New Area,Nanjing,China