

SARS-CoV-2
Antigen Test Kit
(LFIA)

MEDOMICS

Company Profile

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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.



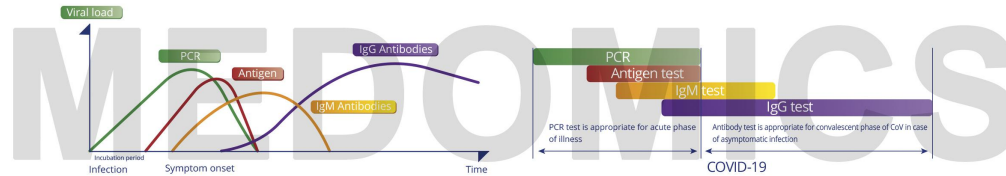
Testing Methods for SARS-CoV-2

SARS-CoV-2 Antigen Test Kit (LFIA)

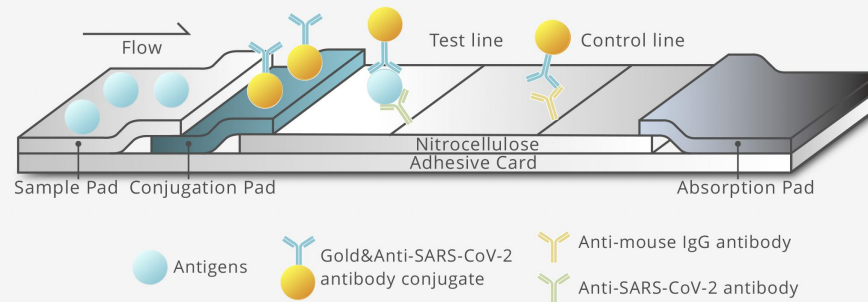
SARS-CoV-2 Antigen Test Kit(LFIA)

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 Medomics SARS-CoV-2 Antigen Test Kit (LFIA) was evaluated with different clinical samples whose status was confirmed by RT-PCR. The results are shown in following tables.

1. Table 1 Nasopharyngeal or throat secretion collection

Medomics SARS-CoV-2 Ag Test	RT-PCR		
	Positive	Negative	Total
Positive	215	2	217
Negative	5	405	410
Total	220	407	627

Sensitivity: 97.73% (94.78%-99.26%)

Specificity: 99.51% (98.24%-99.94%)

Positive predictive value: 99.08% (96.71%-99.89%)

Negative predictive value: 98.78% (97.18%-99.60%)

Accuracy: 98.88% (97.71%-99.55%)

2. Table 2 Anterior Nasal secretion collection

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

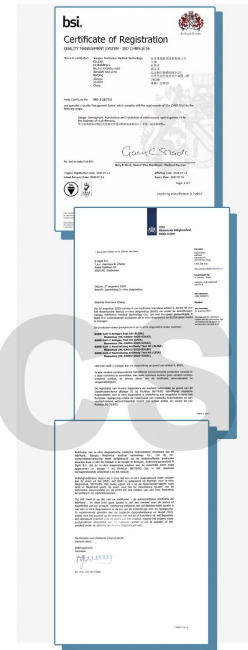
Sensitivity: 95.54% (89.89%-98.53%)

Specificity: 99.04% (94.76%-99.98%)

Positive predictive value: 99.07% (94.95%-99.98%)

Negative predictive value: 95.37% (89.53%-98.48%)

Accuracy: 97.22% (94.05%-98.97%)



Limit of Detection (LoD) Study Results

Concentration TCID ₅₀ /mL	Number Positive/Total	% Detected
10	20/20	100%

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)



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

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The diagram illustrates the test procedure in several steps:

- Preparation:** Shows three methods to open the test strip: Type I (twist), Type II (tear), and Type III (twist and squeeze out all the lysis buffer).
- Insertion:** Shows the swab being inserted into the test strip.
- Extrusion:** Shows the test strip being extruded, with a magnification of X5.
- Click:** Shows the test strip being clicked into the reader, with a magnification of X4.
- Incubation:** Shows the test strip in the reader for 15 minutes.
- Results:** Shows three possible outcomes: Positive (C and T lines), Negative (C line only), and Invalid (no lines).

Key features of the kit:

- Direct Detection of virus
- Easy & Fast operation
- High Sensitivity and Specificity
- No Instruments Required




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