ALSO SUITABLE FOR SAMPLING IN THE ANTERIOR NASAL AREA

SARS-CoV-2 antigen Test Kit (LFIA)

Instructions For Use

INFECTIOUS DISEASE

Product Name

SARS-CoV-2 antigen Test Kit (LFIA)

Product Types And Specifications

Types: I/II/III Test cassette: 1pc/bag Kit: 20 pcs/box, 50 pcs/box, 100 pcs/box

Intended Use

Medomics SARS-CoV-2 antigen Test Kit (LFIA) is used to qualitatively detect SARS-CoV-2 in human samples in vitro.

Coronavirus (CoV) belongs to the order Nidovirales under the Coronaviridae family with 4 genera: α, β, γ and δ. The α and β genera are only pathogenic to mammals, while γ and δ genera mainly cause bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence supporting fecal-oral transmission.

7 kinds of human coronaviruses (HCoV) that cause human respiratory diseases have been identified so far, including: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2. SARS-CoV-2 is one of the most contagious viral pathogens that cause human respiratory tract infections (RTI). Currently, the patients infected by SARS-CoV-2 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 clinical manifestations include fever, fatigue, cough and other symptoms, accompanied by dyspnea, which can rapidly develop into life-threatening severe pneumonia, respiratory failure, acute respiratory vesicle syndrome, septic shock, multiple organ failure, and severe metabolic acid-base imbalance.

Test Principle

Medomics SARS-CoV-2 antigen Test Kit (LFIA) detects the SARS-CoV-2 with colloidal gold immunochromatography using a double antibody sandwich assay. The test cassette contains (1) colloidal gold-labeled anti-SARS-CoV-2 antibody, (2) one detection T line and one quality control C line fixed on a nitrocellulose membrane. T line is fixed with another anti-SARS-CoV-2 antibody for detecting SARS-CoV-2. The quality control antibody is fixed on the C line.

When the appropriate amount of test sample treated with lysis buffer is added to the sample well of the test cassette, the sample will move forward along the test strip via capillary action. If the sample contains SARS-CoV-2 antigens and concentration of antigens is higher than the limit of detection, the antigens will bind to the colloidal gold-labeled anti-SARS-CoV-2 antibody. The immune complex will be captured by another anti-SARS-CoV-2 antibody immobilized on the membrane, forming a red T line and indicating a positive result for SARS-CoV-2. If the sample contains no SARS-CoV-2 antigens or the antigen concentration is lower than the limit of detection, a negative result is displayed.

Additionally, the test cassette also contains a quality control C line. Regardless of what antigens are present,the C line should appear to indicate that the sample has been transported properly through the membrane. If the C line does not appear, it indicates that the test result is invalid and the sample is required to retest.

Test Kit Contents

Type I test kit contains test cassettes,sterile swabs,sampling tubes, a vial containing lysis buffer, droppers and instructions for use.
Type II test kit contains test cassettes, sterile swabs, sampling tubes containing individual lysis buffer, droppers and instructions for use.
Type III test kit contains test cassettes, sterile swabs, sampling tubes, buffer capsules containing individual lysis buffer, droppers and instructions for use.
• Test cassette contains test strip, cassette, desiccant. The test strip contains colloidal gold-labeled anti-SARS-CoV-2 antibody, nitrocellulose membrane (C line fixed with goat-anti-mouse IgG polyclonal antibody, and T line fixed with another anti-SARS-CoV-2 antibody).

Warnings and Precautions

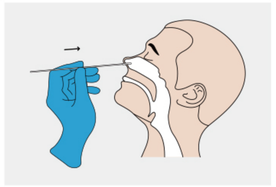
- This test kit is used for in vitro diagnosis only.
- This test kit should be used by qualified personnel with professional experience or proper training.
- This test kit should be used within 1 hour after opening the package, and samples from transport media will reduce sensitivity. The test cassette should not be used if being wet or polluted.
- Proper protection should be taken during testing to avoid splashing when adding sample.
- Dispose of all used or damaged test cassettes, sampling tubes, droppers, swabs, or other kit components as biohazardous materials.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.

Storage Instructions

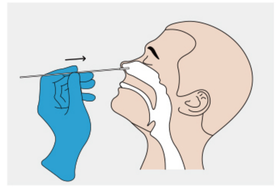
The test kit should be stored away from direct sunlight at 2℃ to 30℃ with a shelf-life of 24 months. Do not freeze.

Sample Requirements

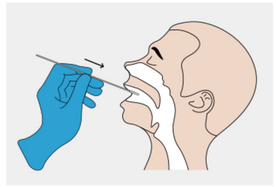
One test cassette can only be used to test one sample type. Sample types include nasopharyngeal secretion, throat secretion and nasal secretion.



• **Anterior Nasal Sampling**: Insert the swab (stick with larger absorbent tip) into a nostril (2.5 cm). Be sure to collect any nasal drainage that may be present. Carefully rotate the swab in a circular path against the inside of the nostril at least 5 times. Using the same swab repeat the procedure in the other nostril.



• **Nasopharyngeal secretion collection**: Take out a (fine or small swab) from the pouch. Insert the swab into one of the patient's nostrils until it reaches the posterior nasopharynx where there is the most secretion, gently rotate and rub the swab over the surface of the posterior nasopharynx for several times before taking it out.



• **Throat secretion collection**: Insert the whole swab (with the larger absorbent tip) completely into the throat from the mouth, centering on the throat wall and the reddened area of the palate tonsil, wipe both sides of the pharyngeal tonsil and posterior pharyngeal wall with moderate force. Try to avoid the tongue before taking it out.

Sample should be treated with lysis buffer provided in this kit as soon as possible after collection. If the sample cannot be processed immediately, it should be stored immediately in a dry, sterilized and strictly sealed plastic tube. It can be stored at 2°C-8°C for 8 hours. Could be stored at -70°Cfor long term storage.

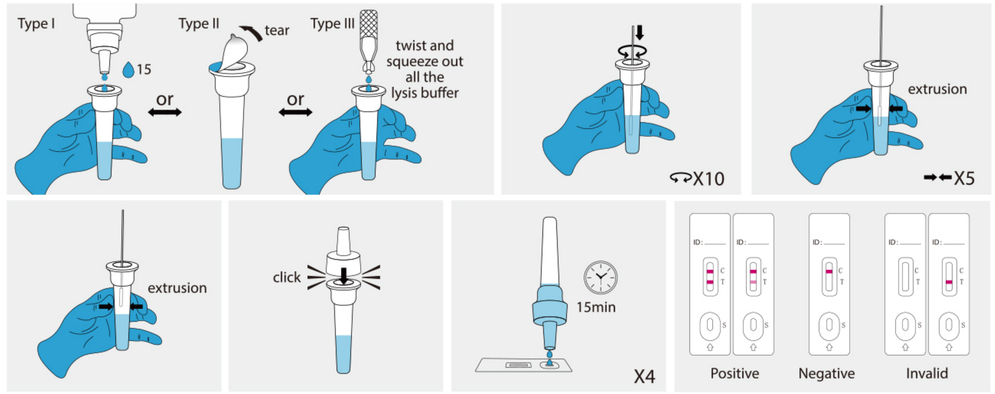
Test Procedure

Do not open pouch until ready to use. Prep necessary materials: Timer | Tube rack for sampling tubes and specimens | Any necessary personal protective equipment.

1 | Sampling: vertically add 15 drops (approximately 350 µL) lysis buffer into the sampling tube from vial or open the seal of the sampling tube containing lysis buffer or twist and squeeze out all the lysis buffer into the sampling tube from capsule. Insert the swab (after collection) into the buffer. Rotate the swab against the inner tube wall 10 times and squeeze the swab from the outer tube wall 5 times to completely dissolve the sample in the buffer, then move the swab up until it is resting on the sample solution, squeeze the swab from the outer tube wall in order to leave the sample in the tube as much as possible. Remove and discard the swab, cover the tube with the dropper.

2 | Test procedures: Open the aluminum foil pouch, take out the test cassette and lay it on a clean flat surface, then mark the cassette with the patient ID or sample number and add 4 drops (approximately 100 µL) processed sample extract into the sample well.

The result should be observed within 15-20 minutes. Results observed after 20 minutes are invalid.



Test Method Limitations

- The accuracy of the test is dependent on the quality of the sample. Improper sampling or storage, using expired samples or repeated frozen-thawed samples can affect the test result. Test results can also be affected by temperature and humidity.
- Negative results may be caused by low concentration of SARS-CoV-2 antigens in the sample and therefore cannot completely rule out the possibility of infection.
- Some medication (e.g. high concentration of over-the-counter (OTC) or prescription medication such as nasal spray) in the collected samples may interfere with the test result. Please perform the test again if the result is in doubt.
- This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
- The results of this test are for clinical reference only and should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods.

Display of Results/Expected Values

- Negative result: If only the quality control C line appears and the detection T line is not visible, the sample contains no SARS-CoV-2 antigens or the SARS-CoV-2 antigens concentration is lower than the limit of detection and the result is negative.
- Positive result: If both the quality control C line and the detection T line appear, then the SARS-CoV-2 antigens have been detected and the result is positive.
- Invalid result: If the C line does not appear, the result is invalid and a new test must be performed.

Note: The color intensity of the T line is related to the concentration of SARS-CoV-2 antigens contained in the sample, and the result should be determined by whether the T line is colored or not regardless of the color intensity.

External Positive and Negative Controls

The external controls consist of positive swab and negative swab are available. Only one red colored C line in the observation window can be seen while using a negative control swab. Both red colored C line and T line in the observation window can be seen while using a positive control swab. If necessary, please contact your local vendor or Medomics to obtain control swabs.

Product Performance

- Limit of Detection - LoD

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2 at which ≥95% of all (true positive) replicates test positive. Dilute the SARS-CoV-2 with lysis buffer to a final concentration gradient of 5, 10, 50, 100, 200, 1000 $TCID_{50}$/mL.

SARS-CoV-2 tested ($TCID_{50}$/mL)	Test Result
1000	20/20 positive
200	20/20 positive
100	20/20 positive
50	20/20 positive
10	20/20 positive
5	12/20 positive

- Cross Reactivity

Cross reactivity and potential interference of Medomics SARS-CoV-2 antigen Test Kit (LFIA) were evaluated by testing commensal and pathogenic microorganisms listed in the following table that may be present in the clinical samples. Each of the bacterium, viruses, and yeast was tested in triplicate with no false positive results.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	No
Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No
MERS-coronavirus	1.0 x 10^5 $TCID_{50}$/mL	No
SARS-coronavirus	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H1N1	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H3N2	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H5N1	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H7N9	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza B Victoria	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza B Yamagata	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus Type 1	1.0 x 10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	1.0 x 10^5 $TCID_{50}$/mL	No
Enterovirus CA16e	1.0 x 10^5 $TCID_{50}$/mL	No
Adenovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No
Staphylococcus aureus	1.0 x 10^6 CFU/mL	No
Staphylococcus epidermidis	1.0 x 10^6 CFU/mL	No
Bordetella pertussis	1.0 x 10^6 CFU/mL	No
Legionella pneumophila	1.0 x 10^6 CFU/mL	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No
Haemophilus influenzae	1.0 x 10^6 CFU/mL	No
Mycobacterium tuberculosis	1.0 x 10^6 CFU/mL	No
Candida albicans	1.0 x 10^6 CFU/mL	No

- Endogenous Interfering Substances Effect

A study was performed to evaluate and demonstrate that the endogenous substances naturally present or drugs that may be artificially introduced into clinical samples do not inference with the detection of SARS-CoV-2 in the Medomics SARS-CoV-2 antigen Test Kit (LFIA) at the concentrations listed below.

Substance	Potential Interfering Substances	Concentration	Interference (Yes/No)
Endogenous	Mucin	2 % w/v	No
	Whole Blood	5 % v/v	No
Nasal spray or drops	Phenylephrine	0.05 mg/ml	No
Nasal steroids	Dexamethasone	0.8 mg/ml	No
	Triamcinolone acetonide	0.8 mg/ml	No
	Budesonide	0.5 mg/ml	No

- Clinical Performance

The performance of Medomics SARS-CoV-2 antigen Test Kit (LFIA) was established with 627 nasopharyngeal or throat swabs collected from patients. Two swabs were collected from one patient and one swab was tested directly using Medomics SARS-CoV-2 antigen Test Kit (LFIA). The real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was used as the comparator method to confirm the status of samples for this study.

RT-PCR			
Medomics Ag test	Positive	Negative	Total
Positive	215	2	217
Negative	5	405	410
Total	220	407	627
*95% Confidence Interval			
Sensitivity: 97.73% (94.78%-99.26%) Specificity: 99.51% (98.24%-99.94%)	PPV: 99.08% (96.71%-99.89%) NPV: 98.78% (97.18%-99.60%)	Accuracy: 98.88% (97.71%-99.55%)	

The performance of Medomics SARS-CoV-2 antigen Test Kit (LFIA) was established with 216 anterior nasal swabs collected from patients. Two swabs were collected from one patient and one swab was tested directly using Medomics SARS-CoV-2 antigen Test Kit (LFIA). The real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was used as the comparator method to confirm the status of samples for this study.

RT-PCR			
Medomics Ag test	Positive	Negative	Total
Positive	107	1	108
Negative	5	103	108
Total	112	104	216
*95% Confidence Interval			
Sensitivity: 95.54% (89.89%-98.53%) Specificity: 99.04% (94.76%-99.98%)	PPV: 99.07% (94.95%-99.98%) NPV: 95.37% (89.53%-98.48%)	Accuracy: 97.22% (94.05%-98.97%)	

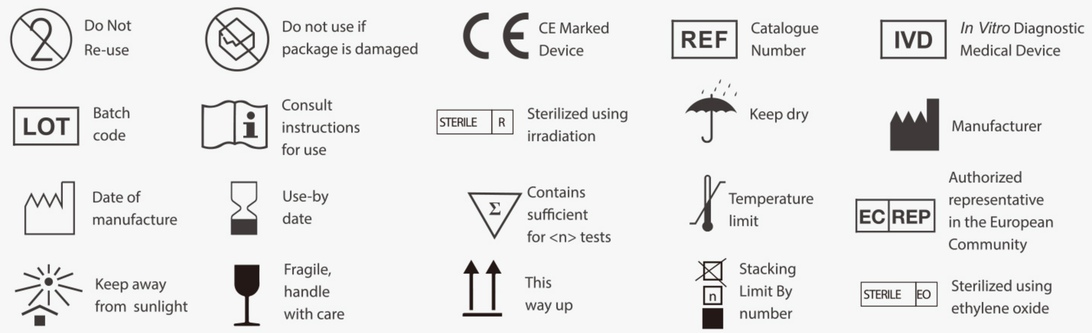
Mutation Virus Detection Compatibility Tips

The Medomics antigen test kit detects the nucleocapsid protein, NOT the spike protein of SARS-CoV-2. The British mutation of B.1.1.7 is at positions 235 and 3 on the nucleocapsid protein, the mutation of the South African variant B.1.351 is at position 205 on the nucleocapsid protein. The Brazilian mutation B.1.1.28 is at position 80 on the nucleocapsid protein. All of these positions are not in the core binding area of the Medomics antibody and therefore do not affect the test results.

[References]

1 | LY Wang, PR Chen, G W Zheng, et al. Research progress on novel coronavirus test methods. Modern Medicine and Clinic, 2020, 35(3): 411-416.

2 | K Tugba, W Ralph, L Hakho. Molecular and Immunological Diagnostic Tests of COVID-19: Current Status and Challenges. IScience, 2020, 23 (8): Doi: 10.1016/j.isci.2020.101406



EC REP
R Sight B.V.
Roald dahllaan 47,5629 MC, Eindhoven.
The Netherlands
Registration Number: 76704726
Tel: 0031640845545 E-mail: info@rsight.nl

Jiangsu Medomics Medical Technology Co.,Ltd.
F3, BuildingC, No.3-1 XinjinhuRoad, Jiangbei New Area,
Nanjing, Jiangsu, China.
Tel: (+86)025-58601060/ (+86)025-58601213
Fax: 025-58601060 E-mail: info@medomics-dx.com

CE
V1.0.05A

Effevtive date: February 15, 2021