SARS-CoV-2 Antigen Test Kit (LFIA)

FOR *IN VITRO* DIAGNOSTIC USE ONLY.
FOR SELF-TESTING.
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST.

EN

Test cassette: 1pc/bag

REF	Specification
1031-14-01	1 pc/Box
1031-34-01	5 pcs/Box
1031-54-01	20 pcs/Box

Display of the anterior nasal swab in original size.

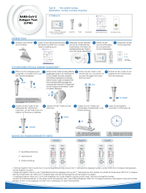
KIT CONTENTS

Test Cassette (individually in a foil pouch with desiccant)


Lysis Buffer


Dropper

Anterior Nasal Swab (CE 0197)

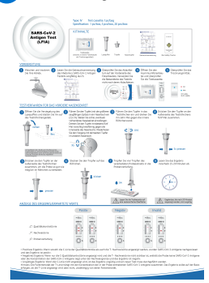

Instructions For Use (IFU)

Bio-Safety Bag

PREPARATION

1 Wash and dry hands.

2 Carefully read IFU.

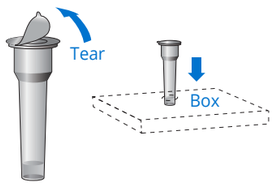


3 Check the expiry date on the foil pouch.

⚠ This test kit should be used within 1 hour after opening the foil pouch.

ANTERIOR NASAL SECRETION TEST PROCEDURE

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

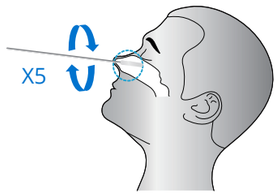


For specification of 1 pc/box and 5 pcs/box, the package box can be used as test-tube rack by pushing the dotted holes on the box
For 20pcs/box, please use the provided test-tube rack in the box

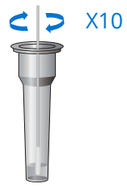
2 Insert the swab (stick with larger absorbent tip) into a nostril (2.5 cm). Be sure to collect any nasal drainage that may be present.

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.



3 Insert the swab into the lysis buffer and rotate the swab against the inner tube wall 10 times.



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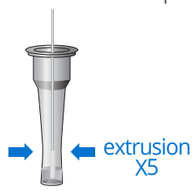
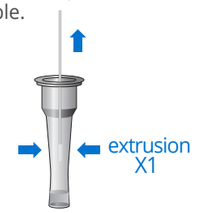
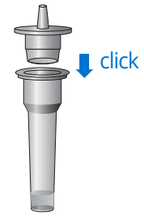
4 Squeeze the swab from the outer tube wall 5 times.
Lift the swab above the buffer solution, squeeze the swab from the outer tube wall one time to leave the sample in the tube as much as possible.



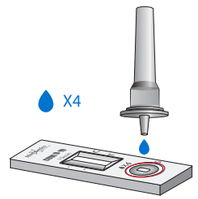


5 Cover the tube with the dropper.



6 Add 4 drops processed sample extract into the sample well.

⚠ Open the foil pouch, then lay the test cassette on a clean flat surface



7 Read the results within 15-20 mins.

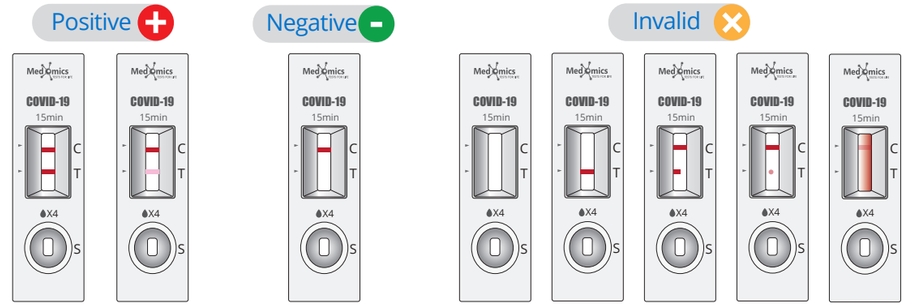
⚠ Result observed after 20 mins is invalid

Remark: Additional required but not provided equipment: Timer

Dispose all those used materials into Bio-safety bag and seal well.

DISPLAY OF THE RESULT / EXPECTED VALUES

"C": Quality Control Line
"T": Detection Line
"S": Sample Well



• **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.

• **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.

• **Invalid result:** If C line does not appear, T line is not complete, or a reddish-purple background affects the interpretation, 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. The result should be determined by whether the T line is colored or not, regardless of the color intensity.

WARNINGS AND PRECAUTIONS

If the test result is positive:
• There is a suspicion of COVID-19
• Contact your doctor / general practitioner or the local health department immediately
• Comply with the local guidelines for self-isolation
• Carry out a PCR confirmation test
If the test result is negative:
• Continue to comply with all applicable rules regarding contact with others and protective measures
• There may be an infection even if the test is negative
• If it is suspected, repeat the test after 1 - 2 days, as the coronavirus cannot be precisely detected in all phases of infection
If the test result is invalid:
• Possibly caused by incorrect test execution
• Repeat the test
• If the test results remain invalid, contact doctor or COVID-19 test center
This test kit is used for self-testing.
This test kit is used for in vitro diagnosis only.
This test kit is designed for individuals by 18 or older.
Bring the kit contents to room temperature before testing.
Negative results do not rule out SARS-CoV-2 infection,particularly in those who have been in contact with patients.
Do not re-use.
Do not use the test kit if the pouch is damaged, the seal is broken or the test cassette is wet or polluted.
Do not use the test kit contents expired.
When collecting an anterior nasal swab sample, use only the Anterior Nasal Swab provided in the Kit.

⚠ Please DO NOT take any decision of medical relevance without consulting your doctor/general practitioner.

⚠ Keep out of reach of children

Medomics TESTS FOR LIFE

SARS-CoV-2 Antigen Test Kit (LFIA)

Introduction

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 novel coronavirus 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.

Intended Use

SARS-CoV-2 Antigen Test Kit (LFIA) is a colloidal gold immunochromatography for the rapid qualitative detection of SARS-CoV-2 nucleocapsid antigens present in human anterior nasal samples in vitro. The test kit is designed for use as self-testing. This test kit is intended use for individuals by 18 or older with clinical symptoms of SARS-CoV-2 infection or who are suspected of COVID-19. If the suspetced individual exhibits respiratory symptoms or suspected to be infected, it is recommended to combine PCR test, clinical symptoms, prevalence and further clinical data to confirm the diagnosis.

Test Principle

SARS-CoV-2 Antigen Test Kit (LFIA) detects the SARS-CoV-2 nucleocapsid antigens with colloidal gold immunochromatography using a double antibody sandwich assay. The test cassette contains (1) colloidal gold-labeled anti-SARS-CoV-2 Nucleocapsid Protein 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 Nucleocapsid Protein 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 nucleocapsid antigens and concentration is higher than the limit of detection, the antigens will bind to the colloidal gold-labeled anti-SARS-CoV-2 Nucleocapsid Protein antibody.

The immune complex will be captured by another anti-SARS-CoV-2 Nucleocapsid Protein 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 nucleocapsid antigens or concentration is lower than the limit of detection, a negative result is displayed.

Internal Quality Control

The test cassette contains a quality control C line. Regardless of what nucleocapsid 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 be retested.

Mutation Virus Detection Compatibility Tips

SARS-CoV-2 Antigen Test Kit(LFIA) detects Nucleocapsid protein, NOT spike protein of SARS-CoV-2. The mutations of SARS-CoV-2 variants B.1.1.7/B.1.351/P.1/B.1.617.1/B.1.617.2 /B.1.526/B.1.427/B.1.429 should be confirmed. And all those variants Nucleocapsid proteins can be effectively detected by SARS-CoV-2 Antigen Test Kit(LFIA).

Kit Contents

Specification	Test Cassette	Anterior Nasal Swab	Lysis Buffer	Dropper	Bio-Safety Bag	Instruc-tions For Use	Test-tube Rack
1 pc/Box	1	1	1	1	1	1	Please use the package box
5 pcs/Box	5	5	5	5	5	1	Please use the package box
20 pcs/Box	20	20	20	20	20	1	1

• Test cassette contains test strip, plastic cassette, desiccant. The test strip contains colloidal gold-labeled anti-SARS-CoV-2 Nucleocapsid Protein antibody, nitrocellulose membrane (C line fixed with goat-anti-mouse IgG polyclonal antibody, and T line fixed with another anti-SARS-CoV-2 Nucleocapsid Protein antibody)

Disposal Instructions

Put all used components back into bio-safety bag. Follow the applicable regulations when disposing.

Storage Instructions

• The test kit should be stored away from direct sunlight at 2°C to 30°C with a shelf-life as detailed on the primary package.
• This test kit should be used within 1 hour after opening the foil pouch.

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.
• For the detection of novel coronavirus and possible subtypes (mutant strains), the changes of epitopes caused by mutation sites of Nucleocapsid Protein may reduce the analytical sensitivity of the reagent and lead to false negative results.

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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. For this purpose the SARS-CoV-2 wild type was diluted with lysis buffer to a final concentration gradient of 5, 10, 50, 100, 200, 1000 $TCID_{50}$/mL. The LOD： 10 $TCID_{50}$/mL.

SARS-CoV-2 wild type 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

• Verification of Variants
SARS-CoV-2 Antigen Test Kit (LFIA) can detect the recombinant nucleocapsid antigens of SARS-CoV-2 variants listed below.

WHO label	Alpha	Beta	Gamma	Kappa	Delta	Iota	Epsilon
Pango lineage	B.1.1.7	B.1.351	P.1	B.1.617.1	B.1.617.2	B.1.526	B.1.427/B.1.429

• Cross Reactivity
Cross reactivity and potential interference of SARS-CoV-2 Antigen Test Kit (LFIA) were evaluated by testing commensal and pathogenic microorganisms diluted with nasal swabs as sample matrix in the absence or presence of heat inactivated SARS-CoV-2 virus. The listed items in the following table 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
Human coronavirus HKU1	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

• 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.Dilute tested items with nasal swabs as sample matrix in the absence or presence of heat inactivated SARS-CoV-2 virus.

Type	Potential Interfering Substances	Concentration	Interference(Yes/No)
Endoge-nous Substance	Mucin	2% w/v	No
	Whole Blood	5% w/v	No
	Icteric (Bilirubin)	40 mg/dL	No
	Rheumatoid factor	200 IU/mL	No
	Triglycerides	1.5 mg/L	No
	Hemoglobin	100 mg/L	No
	Anti-nuclear antibody	>1:40	No
	Pregnant	10-fold dilution	No
	Total IgG	90g/L	No
	Total IgM	4g/L	No
	Total IgA	80g/L	No
Exogenous Substance	Mupirocin	0.25% w/v	No
	Tamiflu (Oseltamivir Phosphate)	0.5% w/v	No
	Fluticasone Propionate	5% w/v	No
	Fluconazole	5% w/v	No
	Zincum gluconium (i.e., Zicam)	5% w/v	No
	Alkalol	10% w/v	No
	Phenol	15% w/v	No
	Phenylephrine hydrochloride	15% v/v	No
	Oxymetazolin hydrochloride	15% v/v	No
	Cromolyn	15% w/v	No
	Oxymetazoline	15% w/v	No
	Galphimia glauca, Sabadilla,	20% w/v	No
	Albuterol	0.005 mg/dL	No
	Acarbose	0.03 mg/dL	No
	Oseltamivir	0.04 mg/dL	No
	Chlorpheniramine	0.08 mg/dL	No
	Diphenhydramine	0.08 mg/dL	No
	Glimepiride (Sulfonylureas)	0.164 mg/dL	No
	Chlorothiazide	2.7 mg/dL	No
	Acetylsalicylic acid	3 mg/dL	No
	Amoxicillin	5.4 mg/dL	No
	Ibuprofen	21.9 mg/dL	No
	Beclomethasone	4.79 ng/mL	No
	Indapamide	140 ng/ml	No
	Flunisolide	0.61 μg/mL	No
	Guaiacol glyceryl ether	1 μg/mL	No
	Biotin	1.2 μg/mL	No
	Zanamivir	17.3 μg /mL	No
	Tobramycin	24.03 μg/mL	No
	Sulfur	9.23 μg/mL	No
	Ribavirin	26.7 μg /mL	No
	Ephedrine	0.1 mg/mL	No
	Benzocaine	0.13 mg/mL	No
	Menthol	0.15 mg/mL	No
	Budesonide	0.5mg/mL	No
	Triamcinolone	0.8mg/mL	No
	Dexamethasone	0.8 mg/mL	No
	Sodium chloride with preservatives	4.44 mg/mL	No
	Lopinavir	16.4 μg/L	No
	Ritonavir	16.4 μg/L	No
	Chloroquine phosphate	0.99 mg/L	No
	Ivermectin	4.4 mg/L	No

• Clinical Performance
The performance of SARS-CoV-2 Antigen Test Kit (LFIA) was established with 566 anterior nasal swabs collected from patients with COVID-19 symptoms within 7 days after onset of symptoms. Two swabs were collected from one patient and one swab was tested directly using SARS-CoV-2 Antigen Test Kit (LFIA). Clinical samples were evaluated to be positive or negative using FDA EUA RT-PCR reference method.

	RT-PCR		
Medomics Ag Test	Positive	Negative	Total
Positive	101	0	101
Negative	9	456	465
Total	110	456	566

*95% Confidence Interval

*95% Confidence Interval
Sensitivity: 91.82%(85.04%~96. 19%)
Specificity: 100%(99. 19%~ 100.00%)
PPV: 100%(96. 41%~100.00%)
NPV: 98.06%(96. 36%~99.11%)
Accuracy: 98.41%(97.00%~99. 27%)

[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

CE Marked Device · Do Not Re-use · Do not use if package is damaged · Caution · REF Catalogue Number · IVD In Vitro Diagnostic Medical Device · LOT Batch code · Consult instructions for use · Sterilized using ethylene oxide · This way up · Date of manufacture · Use-by date · Contains sufficient for <n> tests · Temperature limit · EC REP Authorized representative in the European Community · Keep away from sunlight · Fragile, handle with care · Manufacturer · Keep dry · Stacking Limit By number

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