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

INFECTIOUS DISEASE

FOR *IN VITRO* DIAGNOSTIC USE ONLY.
FOR PROFESSIONAL USE ONLY.

Instructions For Use

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

Product Types And Specifications |

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

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 causes 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.
Influenza, usually called flu, is an acute respiratory infection caused by Influenza virus. It is highly contagious. It is mainly spread through coughing and sneezing. It usually breaks out in spring and winter. It is mainly divided into Influenza A and B Influenza virus. Influenza A viruses are highly variable, followed by Influenza B viruses. Therefore, Influenza A viruses are more prevalent and severe, followed by Influenza B viruses. Influenza A includes H1N1, H3N2, H5N1, H7N9, and Influenza B includes Influenza B (Victoria) and Influenza B (Yamagata).

Intended use |

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2, Influenza A and Influenza B virus antigen in anterior nasal swabs from individuals suspected of COVID-19, Influenza A and Influenza B within the first seven days of symptom onset. SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) shall not be used as sole basis to diagnose or exclude SARS-CoV-2, Influenza A and Influenza B infection.

Test Principle |

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 cassette, the sample will move forward along the test strip by capillary action. If the sample contains SARS-CoV-2 and 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, and 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 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.

Mutation Virus Detection Compatibility Tips |

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) detects Nucleocapsid protein, NOT spike protein of SARS-CoV-2. The mutations of B.1.1.7 (United Kingdom) are located at 235 and 3 on Nucleocapsid protein, the mutation of South Africa variant (B.1.351) is at 205 on Nucleocapsid protein, and the mutation of Brazil variant (B.1.1.28) is at 80 on Nucleocapsid protein. All of the mutations are not the core bining areas of Medomics antibody. And all those variants can be effectively detected by Medomics SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA).

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 the SARS-CoV-2 & Influenza A/B test strip and a plastic cassette casing.
SARS-CoV-2 & Influenza A/B Antigen test strip contains anti-SARS-CoV-2 Nucleocapsid Protein antibody labeled with colloidal gold, anti-Influenza A Nucleocapsid Protein antibody labeled with colloidal gold, anti-Influenza B Nucleocapsid Protein antibody labeled with colloidal gold. Another anti-SARS-CoV-2 Nucleocapsid Protein antibody, anti-Influenza A Nucleocapsid Protein antibody and anti-Influenza B Nucleocapsid Protein antibody are fixed on the N line, A line and B line respectively. The N line/A line/B line and control line (C line) are in the detection window on the nitrocellulose membrane.

Warnings and Precautions |

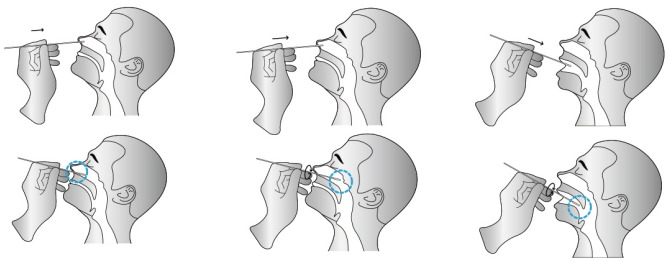
• This test kit is used for in vitro diagnosis only.
• This test kit should be used by qualified person with professional experience or proper training.
• This test kit should be used within 1 hour after opening the package, and samples from transport media will reduce sensitivity. The test cassette 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, Influenza A and Influenza B 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°C to 30°C 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 anterior nasal secretion, nasopharyngeal secretion and throat secretion.



• Anterior Nasal Sampling: Insert the swab 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 swab from the pouch. Insert the swab into one of the patient's nostrils until it reaches the posterior nasopharynx where 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 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°C for long term storage.

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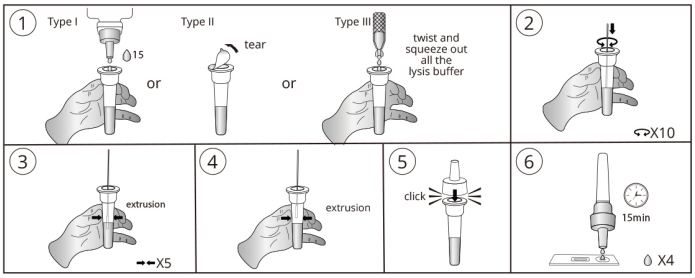
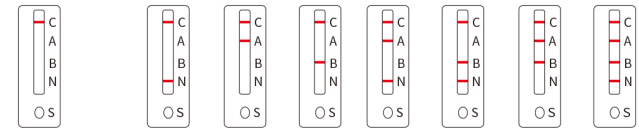
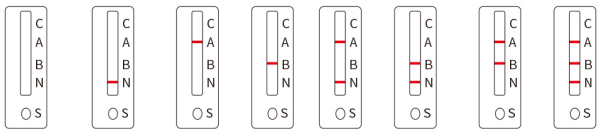
Test Procedure

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.





Negative Positive



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, Influenza A and Influenza B 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 control line (C line) appears and the test line (N line, A line and B line) is invisible, the sample does not contain SARS-CoV-2 and Influenza A/B antigen or the antigen concentration is lower than the limit of detection, then the result is negative.
• SARS-CoV-2 positive result: If the control line (C line) and the test line (N line) appear at the same time, it means that the SARS-CoV-2 has been detected and the result is positive.
• Influenza A positive result: If both the control line (C line) and the Influenza A test line (A line) appear at the same time, it means that Influenza A antigen has been detected in the sample and the result of Influenza A is positive.
• Influenza B positive result : If both the control line (C line) and the Influenza B test line (B line) appear at the same time, it means that Influenza B antigen has been detected in the sample and the result of Influenza B is positive.
• Influenza A/B positive result: If there are three lines of control line (C line), Influenza A test line (A line), Influenza B test line (B line) shown at the same time, it means that Influenza A/B antigen have been detected in the sample.
• Invalid result: If the C line does not appear, the result is invalid and a new test must be performed again.
Note: The intensity of color that the test line area (N line/A line/B line) shows will vary according to the concentration of SARS-CoV-2 antigen, Influenza A antigen and Influenza B antigen. The result should be determined on whether the N line is formed or not, and is irrelevant to the color intensity. Therefore, any intensity of color in the test area (N line/A line/B line) should be considered positive.

External Positive and Negative Controls

External controls include negative control swabs, SARS-CoV-2 positive control swabs, Influenza A virus positive control swabs and Influenza B virus positive control swabs. When using a negative control swab, only a red line can be seen in the observation window (C line). When using the SARS-CoV-2 positive control swab, you can see the red line (C line) and the line (N line) in the observation window at the same time. When using the Influenza A virus positive control swab, you can see the red line (C line) and the line (A line) in the observation window at the same time. When using the Influenza B virus positive control swab, you can see the red line (C line) and the line (B line) in the observation window at the same time. If necessary, please contact your local supplier or Medomics to obtain a control swab.

Product Performance

• Limit of Detection - LoD
Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2, Influenza A and Influenza B at which 100% of all (true positive) replicates test positive.

	Virus Strain	LoD ($TCID_{50}$/mL)
SARS-CoV-2	BetaCoV/JS02/human/2020	10^1
Influenza A	A/Brisbane/02/2018 (H1N1)	10^4
	A/PUERTO/8/1934 (H1N1)	10^2
	A/Kansas/14/2017 (H3N2)	10^2
	A/Aichi/2/1968 (H3N2)	10^2
	A/Anhui/1/2013 (H7N9)	10^4
Influenza B	B/Colorado/06/2017 (Victoria)	10^4
	B/Phuket/3073/2013 (Yamagata)	10^2
	B/Chaoyang Beijing/12977/2017 (Yamagata)	10^4

• Verification of Variants
The performance of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test kit (LFIA) was verified with the recombinant nucleocapsid antigens of SARS-CoV-2 variant B.1.1.7(mutation site: D3L, S235F), B.1.351(mutation site: T205I), B.1.1.28(mutation site: P80R).
• Cross Reactivity
Cross reactivity of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) was 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 were tested in triplicate with no false positive results of SARS-CoV-2 virus, Influenza A and Influenza B.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)		
		SARS-CoV-2	Flu A	Flu B
Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
MERS-coronavirus	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
SARS-coronavirus	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
SARS-CoV-2	1.0 x 10^5 $TCID_{50}$/mL	/	No	No
Influenza A H1N1	1.0 x 10^5 $TCID_{50}$/mL	No	/	No
Influenza A H3N2	1.0 x 10^5 $TCID_{50}$/mL	No	/	No
Influenza A H5N1	1.0 x 10^5 $TCID_{50}$/mL	No	/	No
Influenza A H7N9	1.0 x 10^5 $TCID_{50}$/mL	No	/	No
Influenza B Victoria	1.0 x 10^5 $TCID_{50}$/mL	No	No	/
Influenza B Yamagata	1.0 x 10^5 $TCID_{50}$/mL	No	No	/
Parainfluenza virus Type 1	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
Respiratory syncytial virus	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
Enterovirus CA16e	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
Adenovirus	1.0 x 10^5 $TCID_{50}$/mL	No	No	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No	No	No
Staphylococcus aureus	1.0 x 10^6 CFU/mL	No	No	No
Staphylococcus epidermidis	1.0 x 10^6 CFU/mL	No	No	No
Bordetella pertussis	1.0 x 10^6 CFU/mL	No	No	No
Legionella pneumophila	1.0 x 10^6 CFU/mL	No	No	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No	No	No
Haemophilus Influenzae	1.0 x 10^6 CFU/mL	No	No	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No	No	No
Mycobacterium tuberculosis	1.0 x 10^6 CFU/mL	No	No	No
Candida albicans	1.0 x 10^6 CFU/mL	No	No	No

• Interfering Substances Effect
A study was performed to evaluate and demonstrate that the endogenous substances naturally present or drugs that may be artifcially introduced into clinical samples do not inference with the detection of SARS-CoV-2, Influenza A and Influenza B in the SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) at the concentrations listed below. Dilute tested items with Anterior Nasal Swab as sample matrix in the absence or presence of heat inactivated SARS-CoV-2, Influenza A and Influenza B virus.

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Type	Potential Interfering Substances	Concentration	Interference(Yes/No)
Endogenous 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	90 g/L	No
	Total IgM	4 g/L	No
	Total IgA	80 g/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	0.5 mg/mL	No
	Triamcinolone	0.8 mg/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 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) was established with 627 nasopharyngeal or throat 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 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA). Clinical samples were evaluated to be positive or negative using RT-PCR reference method. Stratification of the positive samples has a sensitivity of 99.24% (n=131, Ct values≤25), 97.67% (n=86, 25＜Ct values≤30) and 33.33% (n=3, Ct values ＞30).

	RT-PCR		
SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)	SARS-CoV-2 Positive	Negative	Total
SARS-CoV-2 Positive	215	2	217
Negative	5	405	410
Total	220	407	627
*95% Confidence Interval			
Sensitivity: 97.73% (94.78%-99.26%)	PPV: 99.08% (96.71%-99.89%)	Accuracy: 98.88% (97.71%-99.55%)	
Specificity: 99.51% (98.24%-99.94%)	NPV: 98.78% (97.18%-99.60%)		

The performance of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) was established with 418 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 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA). Clinical samples were evaluated to be positive or negative using RT-PCR reference method. Stratification of the positive samples has a sensitivity of 98.44% (n=64, Ct values≤25), 97.67% (n=43, 25＜Ct values≤30) and 40% (n=5, Ct values＞30).

	RT-PCR		
SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)	SARS-CoV-2 Positive	Negative	Total
SARS-CoV-2 Positive	208	2	210
Negative	6	202	208
Total	214	204	418
*95% Confidence Interval			
Sensitivity: 97.19%(94.00%~98.96%)	PPV: 99.04%(96.60%~99.88%)	Accuracy: 98.08%(96.26%~99.17%)	
Specificity: 99.01%(96.50%~99.88%)	NPV: 97.11%(93.83%~98.93%)		

[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
3. WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organisation, July 2005.


Do Not Re-use


Keep away from sunlight


Do not use if package is damaged


Keep dry


Consult instructions for use

IVD — *In Vitro* Diagnostic Medical Device

CE Marked Device

REF — Catalogue Number

EC REP — Authorized representative in the European Community

LOT — Batch code

Date of manufacture

Manufacturer

Temperature Limit

Use-by date

STEAILE R — Sterilized using irradiation

Σ — Contains sufficient for <n> tests

Fragile, handle with care

This way up

n — Stacking Limit By number

STEAILE EO — Sterilized using ethylene oxide

EC REP — R Sight B.V.
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