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

Self-testing

EN

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

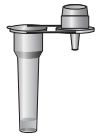
Test cassette: 1pc/bag

REF	Specification
1041-14-01	1 pc/Box
1041-24-01	2 pcs/Box
1041-34-01	5 pcs/Box
1041-54-01	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 and Dropper

Anterior Nasal Swab (CE0197)

Instructions for use

Bio-Safety Bag

PREPARATION

1 Wash and dry hands.

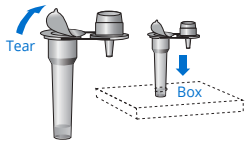
2 Carefully read IFU of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)

3 Check the expiry date at the front of the foil pouch. Do not use kit components after their expiration date.

⚠ 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.

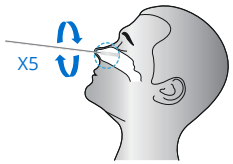


For specification of 1 pc/box、2 pcs/box、5 pcs/box, the package box can be used as test-tube rack by pushing the dotted holes on the box, For 20pcs/box please use the provided test-tube rack in the box.

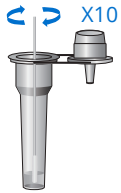
2 Insert the swab (stick with larger absorbent tip) into a nostril (2.5 cm). Be sure to collect any nasal drainage that may be present.

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 sampling tube and rotate the swab against the inner tube wall 10 times.



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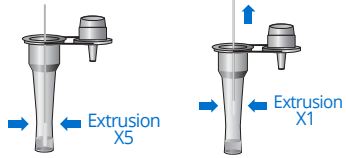
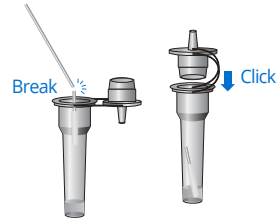
4 Squeeze the swab from the outer tube wall 5 times. Lift the swab above the buffer solution level, squeeze the swab from the outer tube wall one time to leave the sample in the tube as much as possible.

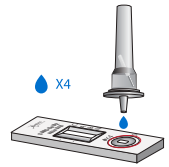


5 Break the swab and cover the tube with the dropper.



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

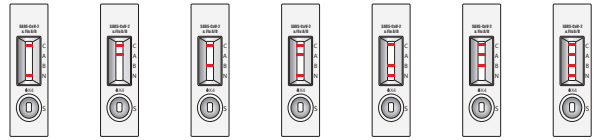
Remark: Additional required but not provided equipment: Timer

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

DISPLAY OF THE RESULT / EXPECTED VALUES

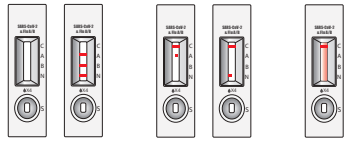
"C": Control Line
"A": Influenza A Test Line
"B": Influenza B Test Line
"N": SARS-CoV-2 Test Line
"S": Sample Well

Positive



Negative

Invalid



• Positive result:
• 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.
If SARS-CoV-2 test result is positive:
• There is currently a suspicion of a COVID-19 infection
• Contact your doctor / general practitioner or the local health department immediately
• Comply with the local guidelines for self-isolation
• Carry out a PCR cofirmational test
If Influenza A/B test result is positive:
• There is currently a suspicion of Influenza A/B infection and the next step should be taken according to local guidelines.

• 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.
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 an infection

• Invalid result:
The test result is invalid if any of the following circumstances apply
1.No C line appears
2.The test line (A line / B line / N line) appears incompletely (all the way access the window)
3.A reddish background of NC film shows on the result window
If the test result is invalid:
• Possibly caused by incorrect test execution
• Repeat the test
• If the test results remain invalid, contact a doctor or a COVID-19 & Influenza A/B test center

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.

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

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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. 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、Influenza A and Influenza B infection or who are suspected of SARS-CoV-2、Influenza A and Influenza B.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 Influenza 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

The SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) detects Nucleocapsid protein, NOT spike protein of SARS-CoV-2. And all of the following variants can be efectively detected by SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA).

WHO label	Alpha	Beta	Gamma	Kappa	Delta	Omicron	Iota	Epsilon
Pango lineage	B.1.1.7	B.1.351	P.1	B.1.617.1	B.1.617.2	B.1.1.529	B.1.526	B.1.427/B.1.429

Contents of the Kit

Components / Specification	Test Cassette	Anterior Nasal Swab	Lysis Bufer and Dropper	Bio-Safety Bag	Instructions for use	Test-tube Rack
For 1 Test/Box	1	1	1	1	1	Please use the package box
For 2 Test/Box	2	2	2	2	1	Please use the package box
For 5 Test/Box	5	5	5	5	1	Please use the package box
For 20 Test/Box	20	20	20	20	1	1

• 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 self-testing (Layman's test).
• 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.
• Proper protection should be taken during testing to avoid splashing when adding sample.
• If SARS-CoV-2 test result is positive，There is currently a suspicion of a COVID-19 infection，Contact your doctor / general practitioner or the local health department immediately，Comply with the local guidelines for self-isolation,Carry out a PCR colrmational test.
• If Influenza A/B test result is positive:There is currently a suspicion of Influenza A/B infection and the next step should be taken according to local guidelines.
• 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.
• Do not re-use the test kit.
• 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 beyond the expiration date printed on the outside of the box.
• When collecting an anterior nasal swab sample, use only the Anterior Nasal Swab provided in the Kit.

Disposal Instructions

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

Keep out of reach of children

Storage Instructions

• The test kit should be stored away from direct sunlight at 2℃ to 30℃ 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 and handling of samples can affect test results.. Test results can also be affected by temperature and humidity.
• Low concentration of SARS-CoV-2, Influenza A and Influenza B antigens in the samplemay cause negative results, so the possibility of infection cannot be completely ruled out.
• 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.

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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^{1}
	A/PUERTO/8/1934 (H1N1)	10^{1}
	A/Kansas/14/2017 (H3N2)	10^{1}
	A/Aichi/2/1968 (H3N2)	10^{1}
	A/Anhui/1/2013 (H7N9)	10^{1}
Influenza B	B/Colorado/06/2017 (Victoria)	10^{1}
	B/Phuket/3073/2013 (Yamagata)	10^{1}
	B/Chaoyang Beijing/12977/2017 (Yamagata)	10^{1}

• Cross Reactivity

Cross reactivityof 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	1.0×10^{5} $TCID_{50}$/mL	No	No	No
Human coronavirus OC43	1.0×10^{5} $TCID_{50}$/mL	No	No	No
Human coronavirus NL63	1.0×10^{5} $TCID_{50}$/mL	No	No	No
Human coronavirus HKU1	1.0×10^{5} $TCID_{50}$/mL	No	No	No
MERS-coronavirus	1.0×10^{5} $TCID_{50}$/mL	No	No	No
SARS-coronavirus	1.0×10^{5} $TCID_{50}$/mL	No	No	No
SARS-CoV-2	1.0×10^{5} $TCID_{50}$/mL	/	No	No
Influenza A H1N1	1.0×10^{5} $TCID_{50}$/mL	No	/	No
Influenza A H3N2	1.0×10^{5} $TCID_{50}$/mL	No	/	No
Influenza A H5N1	1.0×10^{5} $TCID_{50}$/mL	No	/	No
Influenza A H7N9	1.0×10^{5} $TCID_{50}$/mL	No	/	No
Influenza B Victoria	1.0×10^{5} $TCID_{50}$/mL	No	No	/
Influenza B Yamagata	1.0×10^{5} $TCID_{50}$/mL	No	No	/
Parainfluenza virus Type 1	1.0×10^{5} $TCID_{50}$/mL	No	No	No
Respiratory syncytial virus	1.0×10^{5} $TCID_{50}$/mL	No	No	No
Enterovirus CA16e	1.0×10^{5} $TCID_{50}$/mL	No	No	No
Adenovirus	1.0×10^{5} $TCID_{50}$/mL	No	No	No
Mycoplasma pneumoniae	1.0×10^{6} CFU/mL	No	No	No
Staphylococcus aureus	1.0×10^{6} CFU/mL	No	No	No
Staphylococcus epidermidis	1.0×10^{6} CFU/mL	No	No	No
Bordetella pertussis	1.0×10^{6} CFU/mL	No	No	No
Legionella pneumophila	1.0×10^{6} CFU/mL	No	No	No
Streptococcus pneumoniae	1.0×10^{6} CFU/mL	No	No	No
Haemophilus Influenzae	1.0×10^{6} CFU/mL	No	No	No
Streptococcus pneumoniae	1.0×10^{6} CFU/mL	No	No	No
Mycobacterium tuberculosis	1.0×10^{6} CFU/mL	No	No	No
Candida albicans	1.0×10^{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.

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

1. SARS-CoV-2 Test

The performance of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) was established with 1410 anterior nasal swabs collected from patients with COVID-19 symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an anterior nasal swab tested directly using SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) and a nasopharyngeal swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

A summary of the test results for the assessment and comparison reagents is shown in the table below	RT-PCR		
Medomics SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit	SARS-CoV-2 Positive	Negative	Total
SARS-CoV-2 Positive	198	0	198
Negative	31	1181	1212
Total	229	1181	1410

Sensitivity:	198/229	86.46% (81.34%～90.61%)	PPV: 198/198 100.00% (98.15%～100.00%)
Specificity:	1181/1181	100.00% (99.69%～100.00%)	NPV: 1181/1212 97.44% (96.39%～98.26%)
			Accuracy: 1379/1410 97.80% (96.89%～98.50%)

2. Influenza A/B Test

The performance of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) was established with 1410 anterior nasal swabs collected from patients with Influenza symptoms within 7 days after onset of symptoms. Two swabs were collected with the same people, an anterior nasal swab tested directly using SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) and a nasopharyngeal swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

	RT-PCR		
Medomics SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit	FluA /B Positive	Negative	Total
FluA /B Positive	206	0	206
Negative	18	1186	1204
Total	224	1186	1410

Sensitivity:	206/224	91.96% (87.60%～95.17%)	PPV: 206/206 100.00% (98.23%～100.00%)
Specificity:	1186/1186	100.00% (99.69%～100.00%)	NPV: 1186/1204 98.50% (97.65%～99.11%)
			Accuracy: 1392/1410 98.72% (97.99%～99.24%)

[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 | 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 | Keep away from sunlight | Fragile, handle with care | Manufacturer | Keep dry | Stacking Limit By number

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