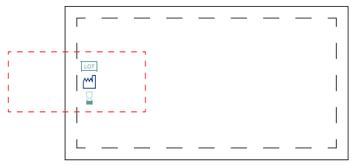
Eight Respiratory Pathogen Antigen Rapid Test Kit (LFIA) Self-testing

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

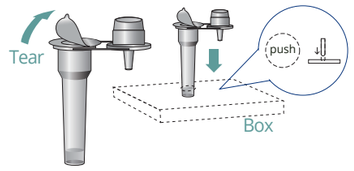
Testing Procedure

1 Equilibrate the kit to room temperature before testing. Wash your hands and dry.

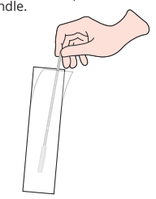
2 Check the expiry date on the box or foil bag. Check that the Test kit contents have not been previously used (these disposable materials cannot be used twice). Do not open pouch until ready to use.



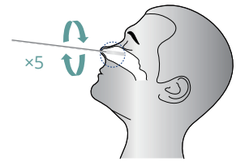
3 Tear the seal of the lysis buffer tube and put it into the test-tube rack.
Note: the package box can be used as test-tube rack by pushing the dotted holes on the box.



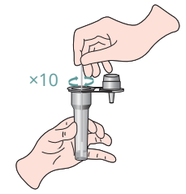
4 Collecting the sample:
Open the package containing the sterile swab. Avoid touching the cotton tip and remove the swab using the plastic handle.



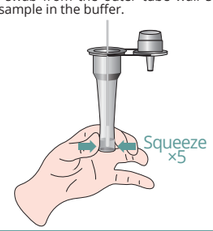
5 Insert the swab into a nostril (2.5 cm). Be sure to collect any nasal drainage that may be present. Carefully rotate the swab in a circular path against the inside of the nostril at least 5 times. Using the same swab repeat the procedure in the other nostril.



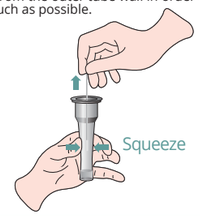
6 After collecting the sample, insert the swab's cotton tip into lysis buffer tube, rotate the swab against the inner tube wall 10 times.



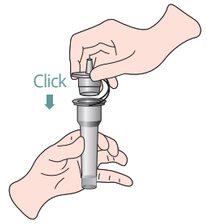
7 Squeeze the swab from the outer tube wall 5 times to completely dissolve the sample in the buffer.



8 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.



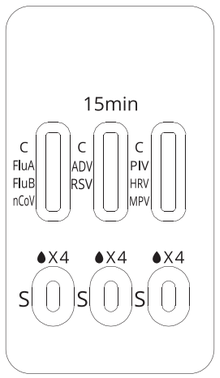
9 Remove and discard the swab, cover the tube with the dropper.



10 Dispense 4 drops (approximately 100 μL) into each of the 3 sample wells of the test cassette. Read the results after 15 minutes. Do not read after 20 minutes.
Note: If the dispensed drop contains air bubbles, add another drop into the well.

11 After testing, dispose all those used materials into Bio-safety bag and seal well. Discard the sealed bag into the waste container in accordance with local regulations.

Display of Results/Expected Values

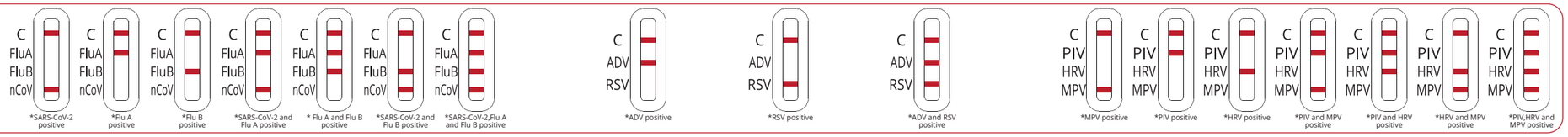


For SARS-CoV-2&Flu A/B (Left)
"C": Control Line "FluA": Influenza A Test Line "FluB": Influenza B Test Line "nCoV": SARS-CoV-2 Test Line "S": Sample Well

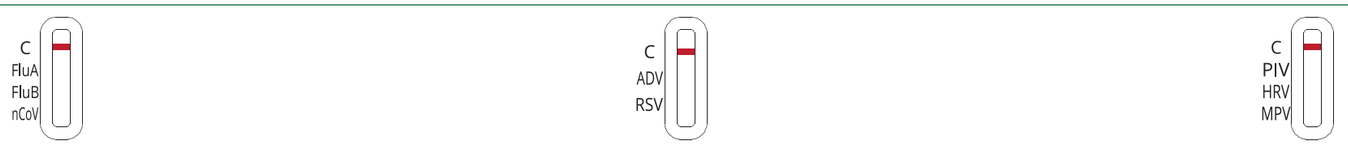
For ADV/RSV (Middle)
"C": Control Line "ADV": ADV Test Line "RSV ": RSV Test Line "S": Sample Well

For PIV/HRV/MPV(Right)
"C": Control Line "PIV": PIV Test Line "HRV ": HRV Test Line "MPV ": MPV Test Line "S": Sample Well

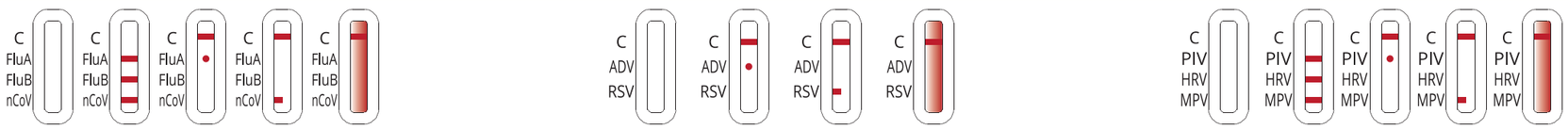
Positive



Negative



Invalid



Negative result: If only the quality control C line appears and the test line is not visible, the sample contains no SARS-CoV-2, Influenza A, Influenza B, ADV, RSV, PIV, HRV, MPV or the concentration is lower than the limit of detection and the result is negative.
Positive result:
• SARS-CoV-2 positive result: If both the control line (C line) and the test line (nCoV line) appear at the same time, it means that SARS-CoV-2 antigen has been detected in the sample and the result of SARS-CoV-2 is positive.
• Influenza A positive result: If both the control line (C line) and the test line (Flu 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 test line (Flu 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.
• ADV positive result: If both the control line (C line) and the test line (ADV line) appear at the same time, it means that ADV antigen has been detected in the sample and the result of ADV is positive.
• RSV positive result: If both the control line (C line) and the test line (RSV line) appear at the same time, it means that RSV antigen has been detected in the sample and the result of RSV is positive.
• PIV positive result: If both the control line (C line) and the test line (PIV line) appear at the same time, it means that PIV antigen has been detected in the sample and the result of PIV is positive.
• HRV positive result: If both the control line (C line) and the test line (HRV line) appear at the same time, it means that HRV antigen has been detected in the sample and the result of HRV is positive.
• MPV positive result: If both the control line (C line) and the test line (MPV line) appear at the same time, it means that MPV antigen has been detected in the sample and the result of MPV is positive.
If the quality control C line appears, and multiple red lines appear in the test line area, indicating that the sample contains multiple respiratory pathogens.
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 (nCoV line/Flu A line/Flu 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 test line is formed or not, and is irrelevant to the color intensity. Therefore, any intensity of color in the test area (nCoV line/Flu A line/Flu B line) should be considered positive.
The intensity of color that the test line area (ADV line/RSV line) shows will vary according to the concentration of ADV antigen, RSV antigen. The result should be determined on whether the test line is formed or not, and is irrelevant to the color intensity. Therefore, any intensity of color in the test area (ADV line/RSV line) should be considered positive.
The intensity of color that the test line area (PIV line/HRV line/MPV line) shows will vary according to the concentration of PIV antigen, HRV antigen and MPV antigen. The result should be determined on whether the test line is formed or not, and is irrelevant to the color intensity. Therefore, any intensity of color in the test area (PIV line/HRV line/MPV line) should be considered positive.

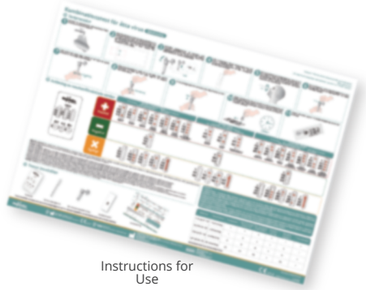
Test Kit contents

Test Cassette

Sterile Anterior Nasal Swab

Lysis Buffer and Dropper(600μL)

Bio-Safety Bag



Instructions for Use

Test kit contains test cassette, sterile anterior nasal swab, Lysis buffer and dropper, bio-safety bag and instructions for use.

REF	Specification	Test Cassette	Sterile Anterior Nasal Swab	Lysis Buffer and Dropper	Instructions For Use	Bio-safety bag
HW-8combo-2026-01	1pc/box	1	1	1	1	1

Materials required but not provided: timer

H&W Biotech

Sterile Anterior Nasal Swab
Jiangsu Rongye Technology Co.,LTD
Touqiao Town, Yangzhou City, Jiangsu Province, China
CE 0197

Sterile Anterior Nasal Swab
EU REP **Riomavix S.L.**
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain

Jiangsu Medomics Medical Technology Co., Ltd.
Building 01, Phase 6, No.71, Xinghui Road, Jiangbei New Area, Nanjing, 210000, Jiangsu, P.R. China
Tel: (+86)025-58601060/ (+86)025-58601213
Fax: 025-58601060
Web: www.medomics-dx.net
E-mail: overseas@medomics-dx.com / support@medomics-dx.com

EU REP **Mega Eurostar Sp. z o. o.**
Add: Obrzeżna, 5 lok.XIP/1, 02-691, Warsaw, Poland
Tel: +48 576 996 942
E-mail: teresa@mega-eurostar.com
info@mega-eurostar.com

Importer: H&W Biotech Oy
Teknikantie 12, 02150 Espoo, Finland
www.healthwing.fi
Email:info@healthwing.fi

Web: www.medomics-dx.net
CE 3018
ReV1.0.00B.EN01
Effective date: 2026-07-07

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. Influenza A viruses and influenza B viruses are thought to be the virus types causing epidemics. 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).
Human adenovirus (ADV) belongs to the adenoviridae family, mammalian adenovirus genus, which is a double-stranded DNA virus without an envelope, mainly infects human respiratory tract, digestive tract and urogenital tract. The main ADV related to respiratory diseases is ADV-B Group (ADV-3, 7, 11, 14, 16, 21, 50, 55), ADV-C Group (ADV-1,2,5,6) and ADV-E group (ADV-4). Acute respiratory adenovirus (ADV) infection which is one of the most common acute respiratory infections in infants and young children. It mainly causes fever, cough, dyspnea and other symptoms.
Respiratory syncytial virus (RSV) belongs to Pneumovirus of Paramyxoviridae with only one serotype, which is a single stranded negative-strand RNA virus with an envelope. RSV infection mainly causes bronchiolitis and pneumonia in infants under 6 months of age and upper respiratory tract infections such as rhinitis and colds in older children and adults.
Human parainfluenza virus (PIV) belongs to the genus Parainfluenza of the Parainfluviridae family. They are single-stranded negative-stranded RNA viruses with cell membranes and have four serotypes. Among them, type 1 and type 2 are primarily associated with asthma exacerbation. Type 3 can cause respiratory diseases in infants and children, such as pneumonia, bronchitis and exacerbate. Type 4 is rarely detected.
Human rhinovirus (HRV) belongs to the genus Enterovirus of the small ribonucleoviridae family. Its genome is a single-stranded posion-stranded RNA with a total length of approximately 7200bp. It encodes 4 structural proteins and 7 non-structural proteins. According to genetic characteristics, it is classified into types A, B and C. Rhinovirus infection can be transmitted through direct contact or airborne droplets. The clinical symptoms include headache, sneezing, runny nose, sore throat, etc. Almost two-thirds of upper respiratory tract infections are caused by rhinoviruses.
Human metapneumovirus (MPV) belongs to the family Pneumoniviridae and the genus Metapneumovirus. It is an enveloped single-stranded negative-stranded RNA virus with an average diameter of approximately 200 nm. MPV includes two genotypes, A and B, and can be divided into four subtypes: A1, A2, B1, and B2. These subtypes are often prevalent simultaneously, and there are no significant differences in the viral transmissibility and pathogenicity among the subtypes. Most MPV infections present as mild self-limiting diseases. Some patients need hospitalization due to complications such as bronchiolitis, pneumonia, acute exacerbation of chronic obstructive pulmonary disease (COPD), and acute attack of bronchial asthma. Those with weakened immune function may progress to severe pneumonia, acute respiratory distress syndrome (ARDS), or multiple organ dysfunction, etc. It even leads to death.

Intended Use

Eight Respiratory Pathogen Antigen Rapid Test Kit (LFIA) is an immunochromatography based one step in vitro test. It is designed for differentiation and qualitative detection of the SARS-CoV-2 virus, Influenza A virus, Influenza B virus, Adenovirus, Respiratory syncytial virus, Parainfluenza virus, Human rhinovirus, metapneumovirus in human anterior nasal swab samples. The test results are used for the auxiliary diagnosis of respiratory pathogen infections, and are suitable for people with clinical symptoms such as fever, sore throat, cough, runny nose. The test kit is designed for use as self-testing. This test kit can be used independently by individuals who are 18 or older. For those under the age of 18, it should be operated or supervised by an adult.
This test kit is not used in combination with other equipment and is not automated.

Test Principle

Eight Respiratory Pathogen Antigen Rapid Test Kit (LFIA) uses a double antibody sandwich method to detect SARS-CoV-2 , Influenza A, Influenza B virus, Adenovirus (ADV), Respiratory syncytial virus (RSV), Parainfluenza virus(PIV), Human rhinovirus (HRV), metapneumovirus (MPV) 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, Influenza A, Influenza B, Adenovirus(ADV), Respiratory syncytial virus (RSV) ,Parainfluenza virus(PIV), rhinovirus (HRV), metapneumovirus (MPV) 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 nCoV line, Flu A line, Flu B line, ADV line, RSV line,PIV line,HRV line, MPV line. If test sample contains SARS-CoV-2 virus, forming a red nCoV line, indicating a positive result for SARS-CoV-2. If test sample contains Influenza A virus, forming a red Flu A line, indicating a positive result for Influenza A. If test sample contains Influenza B virus, forming a red FluB line, indicating a positive result for Influenza B. If test sample contains Adenovirus, forming a red ADV line, indicating a positive result for Adenovirus. If test sample contains Respiratory syncytial virus, forming a red RSV line, indicating a positive result for Respiratory syncytial virus. If test sample contains parainfluenza virus, forming a red PIV line, indicating a positive result for PIV. If test sample contains rhinovirus, forming a red HRV line, indicating a positive result for HRV. If test sample contains metapneumovirus, forming a red MPV line, indicating a positive result for MPV.
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 needs to retest.

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

Sample requirement

The swab sample should be tested immediately after collection.

Test Method Limitations

1.The accuracy of the test is dependent on the quality of the sample. Improper sampling or exposing the sample to unsuitable temperature or humidity before testing will affect the test results. The swab sample should be tested immediately after collection.
2. False negative results may be caused by low concentration of SARS-CoV-2, Influenza A, Influenza B, ADV, RSV, PIV, HRV, MPV antigens in the sample or some use errors can also lead to false negative, therefore cannot completely rule out the possibility of infection.
3. 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.
4. This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
5. The test results of this kit are for clinical reference only and are not the sole basis for clinical diagnosis. The clinical diagnosis and treatment of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.

Clinical performance

A total of 1979 fresh anterior nasal swab samples were collected for testing, and the clinical performance of Eight Respiratory Pathogen Rapid Test Antigen Test Kit (LFIA) was compared with marketed RT-PCR kit. The results are as follows:

1. SARS-CoV-2

Eight Respiratory Pathogen Rapid Test Antigen Test Kit (LFIA)	RT-PCR		
	SARS-CoV-2 Positive	Negative	Total
SARS-CoV-2 Positive	142	0	142
Negative	3	1834	1837
Total	145	1834	1979

Diagnostic sensitivity: 97.93% (94.07%~99.57%) PPV: 100.00% (97.44%~100.00%)
Diagnostic specificity: 100.00% (99.80%~100.00%) NPV: 99.84% (99.52%~99.97%)
Overall concordance rate: 99.85% (99.56%~99.97%) Kappa: 0.9887

2. Flu A

Eight Respiratory Pathogen Rapid Test Antigen Test Kit (LFIA)	RT-PCR		
	Flu A Positive	Negative	Total
Flu A Positive	138	0	138
Negative	5	1836	1841
Total	143	1836	1979

Diagnostic sensitivity: 96.50% (92.03%~98.85%) PPV: 100.00% (97.36%~100.00%)
Diagnostic specificity: 100.00% (99.80%~100.00%) NPV: 99.73% (99.37%~99.91%)
Overall concordance rate: 99.75% (99.41%~99.92%) Kappa: 0.9808

3. Flu B

Eight Respiratory Pathogen Rapid Test Antigen Test Kit (LFIA)	RT-PCR		
	Flu B Positive	Negative	Total
Flu B Positive	136	0	136
Negative	7	1836	1843
Total	143	1836	1979

Diagnostic sensitivity: 95.10% (90.17%~98.01%) PPV: 100.00% (97.32%~100.00%)
Diagnostic specificity: 100.00% (99.80%~100.00%) NPV: 99.62% (99.22%~99.85%)
Overall concordance rate: 99.65% (99.27%~99.86%) Kappa: 0.9730

4. ADV

Eight Respiratory Pathogen Rapid Test Antigen Test Kit (LFIA)	RT-PCR		
	ADV Positive	Negative	Total
ADV Positive	134	0	134
Negative	8	1837	1845
Total	142	1837	1979

Diagnostic sensitivity: 94.37% (89.20%~97.54%) PPV: 100.00% (97.28%~100.00%)
Diagnostic specificity: 100.00% (99.80%~100.00%) NPV: 99.57% (99.15%~99.81%)
Overall concordance rate: 99.60% (99.20%~99.83%) Kappa: 0.9688

5. RSV

Eight Respiratory Pathogen Rapid Test Antigen Test Kit (LFIA)	RT-PCR		
	RSV Positive	Negative	Total
RSV Positive	137	0	137
Negative	8	1834	1842
Total	145	1834	1979

Diagnostic sensitivity: 94.48% (89.42%~97.59%) PPV: 100.00% (97.34%~100.00%)
Diagnostic specificity: 100.00% (99.80%~100.00%) NPV: 99.57% (99.15%~99.81%)
Overall concordance rate: 99.60% (99.20%~99.83%) Kappa: 0.9696

6. HRV

Eight Respiratory Pathogen Rapid Test Antigen Test Kit (LFIA)	RT-PCR		
	HRV Positive	Negative	Total
HRV Positive	131	0	131
Negative	9	1839	1848
Total	140	1839	1979

Diagnostic sensitivity: 93.57% (88.15%~97.02%) PPV: 100.00% (97.34%~100.00%)
Diagnostic specificity: 100.00% (99.80%~100.00%) NPV: 99.57% (99.15%~99.81%)
Overall concordance rate: 99.55% (99.14%~99.79%) Kappa: 0.9696

7. PIV

Eight Respiratory Pathogen Rapid Test Antigen Test Kit (LFIA)	RT-PCR		
	PIV Positive	Negative	Total
PIV Positive	137	0	137
Negative	8	1834	1842
Total	145	1834	1979

Diagnostic sensitivity: 94.48% (89.42%~97.59%) PPV: 100.00% (97.34%~100.00%)
Diagnostic specificity: 100.00% (99.80%~100.00%) NPV: 99.57% (99.15%~99.81%)
Overall concordance rate 99.60% (99.20%~99.83%) Kappa: 0.9695

8. MPV

Eight Respiratory Pathogen Rapid Test Antigen Test Kit (LFIA)	RT-PCR		
	MPV Positive	Negative	Total
MPV Positive	134	0	134
Negative	11	1834	1845
Total	145	1834	1979

Diagnostic sensitivity: 92.41% (86.83%~96.15%) PPV: 100.00% (97.28%~100.00%)
Diagnostic specificity: 100.00% (99.80%~100.00%) NPV: 99.40% (98.94%~99.70%)
Overall concordance rate: 99.44% (99.01%~99.72%) Kappa: 0.9576

Product Performance

• Limit of Detection-LoD
Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2, Influenza A, Influenza B , ADV, RSV, PIV, HRV, MPV at which 95% of all (true positive) replicates test positive. ($TCID_{50}$/ml: The Common units of virulence of live viruses)

	Virus Strain	LoD ($TCID_{50}$/mL)
SARS-CoV-2	BetaCoV/S02/human/2020	$1.0X10^1$
Influenza A	A/Brisbane/02/2018 (H1N1)	$1.0X10^4$
	A/PUERTO/8/1934 (H1N1)	$1.0X10^2$
	A/Kansas/14/2017 (H3N2)	$1.0X10^2$
	A/Aichi/2/1968 (H3N2)	$1.0X10^2$
	A/Anhui/1/2013 (H7N9)	$1.0X10^4$
Influenza B	B/Colorado/06/2017 (Victoria)	$1.0X10^0$
	B/Phuket/3073/2013 (Yamagata)	$1.0X10^2$
	B/Chaoyang Beijing/12977/2017 (Yamagata)	$1.0X10^4$

	Virus Strain	LoD ($TCID_{50}$/mL)
ADV	ADV-1	$1.0X10^5$
	ADV-2	$1.0X10^3$
	ADV-3	$1.0X10^4$
	ADV-4	$1.0X10^4$
	ADV-7	$1.0X10^3$
	ADV-55	$1.0X10^3$
RSV	RSV-A	$1.0X10^4$
	RSV-B	$1.0X10^4$

	Virus Strain	LoD ($TCID_{50}$/mL)
PIV	PIV-1	3.0×10^4
	PIV-2	3.0×10^3
	PIV-3	3.0×10^4
HRV	HRV-A	$1.0X10^4$
	HRV-B	2.0×10^4
	HRV-C	3.0×10^4
MPV	MPV-A	$1.0X10^4$
	MPV-B	$1.0X10^4$

• Cross Reactivity
Cross reactivity of Eight Respiratory Pathogen Antigen 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 commensal and pathogenic microorganisms were tested in triplicate with no false positive results of SARS-CoV-2 virus, Influenza A , Influenza B, ADV, RSV, PIV, HRV, MPV.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)							
		SARS-CoV-2	Flu A	Flu B	ADV	RSV	PIV	HRV	MPV
Human coronavirus OC43	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	No	No
Human coronavirus NL63	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	No	No
Human coronavirus HKU1	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	No	No
Human coronavirus 229E	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	No	No
MERS-coronavirus	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	No	No
SARS-coronavirus	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	No	No
SARS-CoV-2	1.0×10^6 $TCID_{50}$/mL	/	No	No	No	No	No	No	No
H1N1(2009)	1.0×10^6 $TCID_{50}$/mL	No	/	No	No	No	No	No	No
Influenza A H1N1 Seasonal	1.0×10^6 $TCID_{50}$/mL	No	/	No	No	No	No	No	No
Influenza A H3N2	1.0×10^6 $TCID_{50}$/mL	No	/	No	No	No	No	No	No
Influenza A H5N1	1.0×10^6 $TCID_{50}$/mL	No	/	No	No	No	No	No	No
Influenza A H7N9	1.0×10^6 $TCID_{50}$/mL	No	/	No	No	No	No	No	No
Influenza B Victoria	1.0×10^6 $TCID_{50}$/mL	No	No	/	No	No	No	No	No
Influenza B Yamagata	1.0×10^6 $TCID_{50}$/mL	No	No	/	No	No	No	No	No
Enterovirus CA16e	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	No	No
ADV-1	1.0×10^6 $TCID_{50}$/mL	No	No	No	/	No	No	No	No
ADV-2	1.0×10^6 $TCID_{50}$/mL	No	No	No	/	No	No	No	No
ADV-3	1.0×10^6 $TCID_{50}$/mL	No	No	No	/	No	No	No	No
ADV-4	1.0×10^6 $TCID_{50}$/mL	No	No	No	/	No	No	No	No
ADV-7	1.0×10^6 $TCID_{50}$/mL	No	No	No	/	No	No	No	No
ADV-55	1.0×10^6 $TCID_{50}$/mL	No	No	No	/	No	No	No	No
RSV-A	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	/	No	No	No
RSV-B	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	/	No	No	No
PIV-1	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	/	No	No
PIV-2	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	/	No	No
PIV-3	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	/	No	No
HRV-A	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	/	No
HRV-B	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	/	No
HRV-C	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	/	No
MPV-A	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	No	/
MPV-B	1.0×10^6 $TCID_{50}$/mL	No	No	No	No	No	No	No	/
Mycoplasma pneumoniae	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Staphylococcus aureus	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Staphylococcus epidermidis	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Bordetela perussis	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Legionela pneumophila	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Haemophius Influenzae	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Mycobacterium tuberculosis	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Candida albicans	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Streptococcus pyogenes	1.0×10^6 CFU/mL	No	No	No	No	No	No	No	No
Streptococcus dysgalactiae subspecies equisimilis	1.0×10^6 CFU/mL	No	No	No	No	No	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, Influenza B, ADV, RSV, HRV, PIV, MPV in the Eight Respiratory Pathogen Antigen Rapid Test Kit (LFIA) at the concentrations listed below.

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
	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

• Precision
Repeatability:
The repeatability was evaluated by testing negative, weak positive, and strong positive samples in triplicate. All samples were correctly identified ＞99% of the time.
Reproducibility:
The reproducibility was evaluated by conducting triplicate tests on three samples at negative, weak positive and strong positive concentration levels. The testing was performed using three kit lots , two operators across two laboratories over a 20-day period. All samples were correctly identified ＞99% of the time.
• Hook effect
When the SARS-CoV-2 virus level is 10^5 $TCID_{50}$/mL, Influenza A Virus level is 10^5 $TCID_{50}$/mL, Influenza B Virus level is 10^5 $TCID_{50}$/mL, the ADV-1 virus level is 10^7 $TCID_{50}$/mL, the ADV-2 virus level is 10^5 $TCID_{50}$/mL, the ADV-3 virus level is 10^6 $TCID_{50}$/mL, the ADV-4 virus level is $10^6$$TCID_{50}$ /mL, the ADV-7 virus level is 10^5 $TCID_{50}$/mL, the ADV-55 virus level is 10^5 $TCID_{50}$/mL, the RSV-A virus level is 10^6 $TCID_{50}$/mL and the RSV-B virus level is 10^6 $TCID_{50}$/mL, the PIV(1/2/3) virus level is 10^6 $TCID_{50}$/mL , the HRV(A/B/C) virus level is 10^6 $TCID_{50}$/mL , the MPV(A/B) virus level is 10^6 $TCID_{50}$/mL , no hook effect is observed in the test.

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 can be used independently by individuals who are 18 or older. For those under the age of 18, it should be operated or supervised by an adult.
• Equilibrate the kit to room temperature before testing.
• Proper protection should be taken during testing to avoid splashing when adding sample.
• The Lysis Buffer included：Tris, NaCl, EDTA, SDS, Triton X-405 reduced, Triton X- 100, Proclin 300, Purified water. Safety information – warnings with the lysis buffer (Lysis buffer should only be used as directed; do not ingest; do not dip the swab into provided lysis buffer or other liquid before inserting the swab into the nose; avoid contact with skin and eyes; keep out of the reach of children and pets before and after use. If the lysis Buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre).
• If the SARS-CoV-2 test result is positive, there is currently a suspicion of a COVID-19 infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.
• If influenza A/B test result is positive: There is currently a suspicion of influenza A/B infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.
• If ADV test result is positive: There is currently a suspicion of Adenovirus infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.
• If RSV test result is positive: There is currently a suspicion of Respiratory syncytial virus infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.
• If PIV test result is positive: There is currently a suspicion of parainfluenza virus infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.
• If HRV test result is positive: There is currently a suspicion of Human rhinovirus infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.
• If MPV test result is positive: There is currently a suspicion of metapneumovirus infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.
• 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.
• If an invalid result is produced, the user should retest with a new test.
• Do not mix with kit components from other batches.
•The used test cassette, sterile swab, lysis buffer and dropper after the test shall be placed in the bio-safety bag to avoid the potential risk of sample infection. Seal the bio-safety bag and dispose of it according to local regulations.

Notice：If there has any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State.
The Summary of Safety and Performance (SSP) for this product can be accessed via EUDAMED (https://ec.europa.eu/tools/eudamed).

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Version	Change History	Effect Date
ReV1.0.00B.EN01	Initial release	2026-07-07

CE Marked Device | IVD *In Vitro* Diagnostic Medical Device | LOT Batch code | REF Catalogue Number | STERILE EO Sterilized using ethylene oxide | EU REP Authorized representative in the European Community | Do Not Re-use | Do not use if package is damaged and consult instructions for use | Caution | Contains sufficient for <n> tests | Consult instructions for use | Use-by date | Date of manufacture | Manufacturer | 2℃ 30℃ Temperature limit | Fragile, handle with care | Keep away from sunlight | Keep dry