REF RNS92111 Eleven Respiratory Pathogens Antigen Rapid Test Kit
Instructions for use

EN CE

FOR PROFESSIONAL USE ONLY

INTRODUCTION

Acute respiratory infection is a common and frequently occurring disease worldwide. Respiratory virus is an important pathogen of acute respiratory infection. Its clinical manifestations are mainly rhinitis,pharyngitis, laryngitis, Tonsillitis and other symptoms. Severe cases can cause tracheitis, bronchitis andpneumonia. It is the main cause of morbidity and mortality in winter and spring for young children, the elderly and the infirm, and those with low immune function. It has been proven that 80% of acute upper respiratory diseases and most lower respiratory diseases are caused by pathogens outside of bacteria, with respiratory viruses being the most common.

INTENDED USE

This kit is used for in vitro qualitative detection of COVID-19, Influenza A virus(Flu A), Influenza B virus(Flu B),Respiratory syncytial virus(RSV),Adenovirus(ADV),M.Pneumoniae(MP),Chlamydia pneumoniae(CP) ,Human Metapneumovirus(HMPV), Rhinovirus(RhV), Parainfluenza virus 1/3(PIV1/3) and Parainfluenza virus(PIV2) antigen in human nasal swab samples.

PRINCIPLE

The test kit is immunochromatographic and uses latex microspheres method to detection COVID-19, Respiratory syncytial virus, Adenovirus, Influenza A virus, Influenza B virus, Chlamydia pneumoniae, M.pneumoniae,Human Metapneumovirus,Rhinovirus,Parainfluenza virus 1/3 and Parainfluenza virus 2 antigen. During detection, the treated sample is drop into the sample wells of the test card.When the concentration of COVID-19, Respiratory syncytial virus,Adenovirus,Influenza A virus,Influenza B virus , M.pneumoniae,Chlamydia pneumoniae,Human Metapneumovirus,Rhinovirus,Parainfluenza virus 1/3 and Parainfluenza virus 2 in samples are higher than the minimum detection limit, the viral antigen will form complexes with labeled antibodies first. Under chromatography, the complexes move forward along the nitrocellulose membrane till captured by pre-coated monoclonal antibody of COVID-19,Respiratory syncytial virus,Adenovirus,Influenza A virus,Influenza B virus,M.pneumoniae,Chlamydia pneumoniae,Human Metapneumovirus,,Rhinovirus,Parainfluenza virus 1/3 and Parainfluenza virus 2 in detection area (COV / A / B / CP / RSV / ADV /MP / HMPV / RhV /PIV 1/3/2) on nitrocellulose film to form a red reaction line on the detection area at this point the result is positive. Conversely, if there is no viral antigen or the concentration of antigen in sample is below the minimum detection limit, no red reaction line appears in the detection area, at this point the result is negative.Regardless of whether the sample contains viral antigens or not, a red reaction line will appear in the quality control area(C),the red reaction line that appears in the quality control area(C) is the criterion for determining if the chromatography process is normal.

VIRUS MUTATION DETECTION COMPATIBILITY

This test kit detection the nucleocapsid protein, not the spike protein of COVID-19, and all of the following variants can be effectively detection with the test kit.

ALPHA	BETA	GAMMA	KAPPA	DELTA	OMICRON	IOTA	EPSILON
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

WARNINGS AND PRECAUTIONS

- This test kit is for in vitro diagnostic use only.
- Bring the contents of the kit to room temperature before testing.
- Appropriate protection should be worn while performing the test to avoid splashes when adding the sample.
- Do not reuse the test kit.
- Do not use the test kit if the pouch breaks the seal broken or the test cassette is wet or dirty.
- Do not use the contents of the test kit after the expiry date on the expiry date printed on the outside of the packaging.

STORAGE INSTRUCTIONS

- The test kit should be protected from direct sunlight and store at 2 to 30℃, with the shelf life stated on the packaging.
- This test kit should be used within 1 hour of opening the foil bags.

⚠ Keep out of reach of children

COMPONENTS

•Test Card •Sterile Swab •Sample Extraction Buffer •Instruction for Use

DIRECTIONS FOR USE

Allow the test device, sample extraction buffer to equilibrate to room temperature (20- 30°C) prior to testing, blowing the nose before taking a nasal swab .

Nasal Swab Specimen Collection :

1.Remove the swab from the package.

2.Insert swab about 1.5cm into nostril until resistance is met at turbinates.
For young children do not insert more than 1/2 inch.

3.Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.

Specimen Transport and Storage :

After swabbing, process the swab in the extraction buffer as soon as possible. Do not place the swab back into the swab packaging sleeve after specimen collection.
Specimens should be tested within 30 minutes. Do not freeze or transport the sample for later testing.

Testing Procedure :

1.Peel off the aluminum foil seal from a sample extraction tube.

2.Immerse the sampled swab into the sample extraction tube to make the sample extraction buffer completely penetrate the swab, rotate the swab 10 times and squeeze the swab 5 times, leave the swab in the buffer for one minute, otherwise may get false negative results.Remove and discard the swab.

3.Insert the tube cap firmly on the sample extraction tube.Gently shake the extraction tube for about 5 seconds to make sure sample mix well with extraction buffer.

4.Drops 3 drops of mixed sample into the sample hole of test card vertically, start the timer. Read the result at 10 minutes.
**Read the result at 10 minutes. Result after 20 mins will not be valid.

INTERPRETATION OF RESULTS

POSITIVE (+)

- Positive MP: Two red lines in the MP/ 1/3 / 2 test window, a red line in the quality control area(C) and another red line in the detection area(MP) .
- Positive PIV 1/3: Two red lines in the MP/ 1/3 / 2 test window, a red line in the quality control area(C) and another red line in the detection area(1/3).
- Positive PIV 2: Two red lines in the MP/ 1/3 / 2 test window, a red line in the quality control area(C) and another red line in the detection area(2).
- Positive MP/PIV 1/3/2: Four red lines in the MP/ 1/3 / 2 test window, a red line in the quality control area(C),a red line in the detection area (MP) , a red line in the detection area(1/3) and a red line in the detection area(2) .
- Positive CP: Two red lines in the CP/HMPV/RhV test window, a red line in the quality control area(C) and another red line in the detection area(CP) .
- Positive HMPV: Two red lines in the CP/HMPV/RhV test window, a red line in the quality control area(C) and another red line in the detection area(HMPV).
- Positive RhV: Two red lines in the CP/HMPV/RhV test window, a red line in the quality control area(C) and another red line in the detection area(RhV).
- Positive CP/HMPV/RhV: Four red lines in the CP/HMPVRhV test window, a red line in the quality control area(C),a red line in the detection area (CP) , a red line in the detection area(HMPV) and a red line in the detection area(RhV) .
- Positive RSV: Two red lines in the RSV/ADV test window, a red line in the quality control area(C) and another red line in the detection area(RSV).
- Positive ADV: Two red lines in the RSV/ADV test window, a red line in the quality control area(C) and another red line in the detection area(ADV).
- Positive RSV/ADV: Three red lines in the RSV/ADV test window, a red line in the quality control area (C),a red line in the detection area (RSV) and a red line in the detection area(ADV) .
- Positive COV: Two red lines in the COV/Flu A/B test window, a red line in the quality control area(C) and another red line in the detection area(COV).
- Positive Flu A: Two red lines in the COV/Flu A/B test window, a red line in the quality control area(C) and another red line in the detection area(A).
- Positive Flu B: Two red lines in the COV/Flu A/B test window, a red line in the quality control area(C) and another red line in the detection area(B).
- Positive COV/Flu A/B: Four red lines in the COV/FluA/B test window, a red line in the quality control area(C),a red line in the detection area (COV) , a red line in the detection area(A) and a red line in the detection area(B) .

**Note:The intensity of the colour of the lines(MP/PIV 1/3/2/CP/HMPV/RhV/RSV/ADV/COV/A/B) may vary depending on the concentration of COVID-19, ADV, RSV, MP,PIV 1/3/2,CP,HMPV,RhV, Influenza A and influenza B antigens in the sample. Therefore, a positive result is judged as long as there is a confirmed band in the detection area(MP/PIV 1/3/2/CP/HMPV/RhV/RSV/ADV/COV/A/B),even if it is a very faint line. A positive result means that you are likely to be infected with COVID-19, ADV, RSV, MP,CP,HMPV,RhV, PIV 1 / 3/ 2, Influenza A or influenza B.Test results should always be considered in the context of clinical observations and epidemiological data when making final diagnoses and patient management decisions. As recommended by the CDC,you should avoid spreading the virus to others by self-isolating at home and avoiding contact with others.

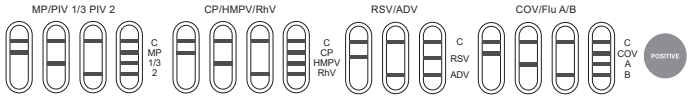

Fig. 1 Positive Result

NEGATIVE (-)

Only a red line appears in the quality control area(C), but not at the detection area(MP/PIV 1/3/2/CP/HMPV/RhV/RSV/ADV/COV/A/B),indicates that COVID-19, ADV, RSV, MP,PIV 1/3/2,CP,HMPV,RhV, Influenza A and influenza B is not detected in thesample,but a negative result does not exclude the absence of COVID-19, ADV, RSV, MP,PIV 1/3/2,CP,HMPV,RhV,Influenza A and influenza B and should not be used as the sole basis for treatment or patient management decisions. Negative results should be considered in the context of the individual's recent exposure history medical history and the presence of clinical signs and symptoms consistent with COVID-19, ADV, RSV, MP,PIV 1/3/2,CP,HMPV,RhV, Influenza A , influenza B and confirmed by PCR testing as necessary for patient management.

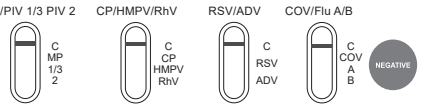

Fig. 2 Negative Result

INVALID

No red line appears in the control area (C) after performing the test. The directions may not have been followed correctly or the test may have failure to function. You need review the instruction for use again and repeat the test with a new test card.

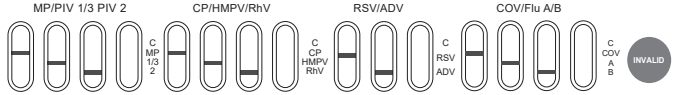

Fig. 3 Invalid Result

TEST METHOD LIMITATIONS

- The accuracy of the test depends on the quality of the sample. Improper sampling or storage, use of expired samples or repeatedly frozen and thawed samples can do this affect the test result. The test results can also by temperature and humidity are affected.
- Low levels of COVID-19, ADV, RSV, MP, PIV, CP,HMPV,RhV, Influenza A and influenza B antigens in the sample can produce negative results, so that an infection cannot be completely ruled out.
- Some medications (such as high levels of over-the-counter or prescription drugs such as nasal spray) in the samples taken may affect the test result. Please perform the test again if the result is doubtful.
- This product is for qualitative testing only. The specific concentration of each indicator must be related to other quantitative methods are measured.
- The results of this test are for clinical reference only and should be used not be the only basis for the diagnosis. The results should be in combination with clinical observations and other test methods be used.

CLINICAL PERFORMANCE

1.COVID-19 test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		COVID-19 Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	COVID-19	Positive	Negative	
	Positive	152	2	154
	Negative	6	180	186
Total Results		158	182	340

Clinical Sensitivity = 152/158=96.20%（95%CI:90.84%~98.46%）
Clinical Specificity =180/182=98.90%（95%CI:96.55%~99.95%）
Accuracy:332/340= 97.65%（95%CI:93.28%~99.55%）

2.RSV test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		RSV Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	RSV	Positive	Negative	
	Positive	153	1	154
	Negative	5	181	186
Total Results		158	182	340

Clinical Sensitivity = 153/158=96.84%（95%CI:91.64%~98.75%）
Clinical Specificity =181/182=99.45%（95%CI:97.18%~99.98%）
Accuracy:334/340= 98.24%（95%CI:94.36%~99.62%）

3.Influenza A/B test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		Influenza A/B Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	Influenza A/B	Positive	Negative	
	Positive	154	1	155
	Negative	4	181	185
Total Results		158	182	340

Clinical Sensitivity = 154/158=97.47%（95%CI:92.84%~98.75%）
Clinical Specificity =181/182=99.45%（95%CI:97.28%~99.90%）
Accuracy:335/340= 98.53%（95%CI:94.76%~99.94%）

4.ADV test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		ADV Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	ADV	Positive	Negative	
	Positive	155	2	157
	Negative	3	180	183
Total Results		158	182	340

Clinical Sensitivity = 155/158=98.10%（95%CI:93.24%~98.56%）
Clinical Specificity =180/182=98.9%（95%CI:97.28%~99.90%）
Accuracy:335/340= 98.53%（95%CI:95.16%~98.83%）

5.MP test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		MP Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	MP	Positive	Negative	
	Positive	157	1	158
	Negative	1	181	182
Total Results		158	182	340

Clinical Sensitivity = 157/158=99.37%（95%CI:95.44%~99.46%）
Clinical Specificity =181/182=99.45%（95%CI:96.87%~99.80%）
Accuracy:338/340= 99.41%（95%CI:96.23%~99.85%）

6.PIV 1/3 test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		PIV 1/3 Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	PIV 1/3	Positive	Negative	
	Positive	154	2	156
	Negative	4	180	184
Total Results		158	182	340

Clinical Sensitivity = 154/158=97.47%（95%CI:96.12%~98.64%）
Clinical Specificity =180/182=98.90%（95%CI:97.34%~99.68%）
Accuracy:334/340= 98.24%（95%CI:97.54%~99.25%）

7.PIV 2 test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		PIV 2 Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	PIV 2	Positive	Negative	
	Positive	155	3	158
	Negative	3	179	182
Total Results		158	182	340

Clinical Sensitivity = 155/158=98.10%（95%CI:97.55%~99.13%）
Clinical Specificity =179/182=98.35%（95%CI:98.11%~99.52%）
Accuracy:334/340= 98.24%（95%CI:97.54%~99.25%）

8.CP test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		CP Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	CP	Positive	Negative	
	Positive	155	1	156
	Negative	3	181	184
Total Results		158	182	340

Clinical Sensitivity = 155/158=98.10%（95%CI:97.82%~99.78%）
Clinical Specificity =181/182=99.45%（95%CI:99.15%~99.93%）
Accuracy:336/340= 98.82%（95%CI:98.95%~99.83%）

9.HMPV test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		HMPV Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	HMPV	Positive	Negative	
	Positive	155	3	158
	Negative	3	179	182
Total Results		158	182	340

Clinical Sensitivity = 155/158=98.10%（95%CI:96.12%~98.94%）
Clinical Specificity =179/182=98.35%（95%CI:97.22%~99.37%）
Accuracy:334/340= 98.24%（95%CI:97.84%~99.36%）

10.RhV test

Contingency Table Analysis of RT-PCR Results and Evaluation Reagent Test Results.

Method		RhV Nucleic Acid Test Kit (RT-PCR)		Total Results
Eleven Respiratory Pathogens Antigen Rapid Test Kit	RhV	Positive	Negative	
	Positive	156	2	158
	Negative	2	180	182
Total Results		158	182	340

Clinical Sensitivity = 156/158=98.70%（95%CI:97.54%~99.24%）
Clinical Specificity =180/182=98.90%（95%CI:98.31%~99.58%）
Accuracy:336/340= 98.82%（95%CI:97.48%~99.57%）

Cross Reaction

The test results are below the corresponding concentration of the substances in the table below, a single virus corresponding to the test card which has no effect on the negative and positive test results of this test card, and there is no cross-reaction.

Species	Name of pathogen	Concentration
Coronavirus	Coronavirus HKU1	1.0 x 10^6copies/mL
	Coronavirus OC43	1.0 x 10^6copies/mL
	Coronavirus 229E	1.0 x 10^6copies/mL
	Coronavirus NL63	1.0 x 10^6copies/mL
Adenovirus	Type 1	1.0 x 10^6copies/mL
	Type 2	1.0 x 10^6copies/mL
	Type 3	1.0 x 10^6copies/mL
	Type 4	1.0 x 10^6copies/mL
	Type 5	1.0 x 10^6copies/mL
	Type 7	1.0 x 10^6copies/mL
	Type 55	1.0 x 10^6copies/mL
Influenza A	Novel Influenza A (H1N1) Virus	1.0 x 10^6copies/mL
	H5N1	1.0 x 10^6copies/mL
	H3N2	1.0 x 10^6copies/mL
	H7N9	1.0 x 10^6copies/mL
	Seasonal H1N1 influenza virus	1.0 x 10^6copies/mL
Influenza B	Yamagata	1.0 x 10^6copies/mL
	Victoria	1.0 x 10^6copies/mL
Respiratory virus	Parainfluenza virus type 1	1.0 x 10^6copies/mL
	Parainfluenza virus type 2	1.0 x 10^6copies/mL
	Parainfluenza virus type 3	1.0 x 10^6copies/mL
	Parainfluenza virus type 4	1.0 x 10^6copies/m
Pneumonia virus	Respiratory syncytial virus type A	1.0 x 10^6copies/mL
	Respiratory syncytial virus type B	1.0 x 10^6copies/mL
Rhinovirus	Rhinovirus A	1.0 x 10^6copies/mL
	Rhinovirus B	1.0 x 10^6copies/mL
	Rhinovirus C	1.0 x 10^6copies/mL
Metapneumovirus	Human metapneumovirus	1.0 x 10^6copies/mL
Enterovirus	Enterovirus A	1.0 x 10^6copies/mL
	Enterovirus B	1.0 x 10^6copies/mL
	Enterovirus C	1.0 x 10^6copies/mL
	Enterovirus D	1.0 x 10^6copies/mL
Lymphophilic viruses	EB virus	1.0 x 10^6copies/mL
Measles virus	Measles virus	1.0 x 10^6copies/mL
Cytomegalovirus	Human cytomegalovirus	1.0 x 10^6copies/mL
Rotavirus	Rotavirus	1.0 x 10^6copies/mL
Norovirus	Norovirus	1.0 x 10^6copies/mL
Mumps virus	Mumps virus	1.0 x 10^6copies/mL
Herpes virus	Herpes zoster virus	1.0 x 10^6copies/mL
Mycoplasma	Mycoplasma pneumoniae	1.0 x 10^6copies/mL
Chlamydia	Chlamydia pneumoniae	1.0 x 10^6copies/mL

Interfering Substances Reaction

When tested using the Eleven Respiratory Pathogens Antigen Rapid Test Kit, there was no interference between the device reagents and the Potential interference substances listed in below table that would create.

Substance	Concentration	Substance	Concentration
Mucin	120mg/dL	Azithromycin	2mg/mL
Human Blood	20% (v/v)	Tobramycin	1.2mg/mL
Phenylephrine	4mg/mL	Histamine Dihydrochloride	10 mg/mL
Oxymetazoline	4mg/mL	Lopinavir	1000mg/mL
Sodium Chloride	40mg/mL	Ritonavir	120mg/mL
Beclomethasone	40mg/mL	Arbidol	1400ng/mL
Dexamethasone	40mg/mL	Ceftriaxone	80μg/mL
Flunisolide	40μg/mL	Meropenem	400mg/mL
Triamcinolone Acetonide	4mg/mL	Peramivir	2mg/mL
Budesonide	4mg/mL	Interferon-α	1600IU/mL
Mometasone	4mg/mL	Ribavirin	20mg/mL
Fluticasone	4mg/mL	Oseltamivir	120ng/mL
Zanamivir	40mg/mL	Levofloxacin	20μg/mL

Symbol

Symbol	Meaning	Symbol	Meaning
IVD	In Vitro Diagnostic Medical Device		Storage Temperature Limit
	Manufacturer	EC REP	Authorized Representative In The European Community
	Date of Manufacture		Use By Date
	Do Not Reuse		Consult Instruction For Use
LOT	Batch Code	CE	CE Conformity Marking

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