This product is for in vitro diagnostic use only and should not be used for any other purposes.
Please read these instructions carefully before use.

TEN RESPIRATORY PATHOGENS ANTIGEN TEST KIT

REF RP1011N-1

CE

USER MANUAL

Latest update:20250804

PRODUCT USAGE

This product is used for in vitro qualitative detection of human metapneumovirus(hMPV), Avian influenza A(H5N1) virus, COVID-19, Influenza A virus(Flu A), Influenza B virus(Flu B), Adenovirus(ADV), Respiratory syncytial virus(RSV), M.Pneumoniae(MP), Parainfluenza virus 1/3(PIV1/3) and Parainfluenza virus 2(PIV 2) antigens in nasal swab samples. It is intended for the rapid testing of ten types of antigens by professionals. Please consult a physician for medical evaluation.

It is applicable for individuals aged 18 and above. Users under 18 years old should perform the test with assistance from an adult. It can detect symptomatic and asymptomatic infections.

PACKAGE CONTENTS

Test Card | User Manual | Sample Extraction Buffer | Sterile Swab | Biohazard Bag | hour meter (Not included in the package)

PREPARATION BEFORE INSPECTION

Before collecting the sample, blow your nose several times. Make sure your hands are clean and dry before performing the test.

Please read the user manual carefully.

Inspect all components of the test kit, and ensure that all components are complete and undamaged.

Check the expiration date printed on the aluminum foil pouch of the test device.

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 and pneumonia. 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 human metapneumovirus(hMPV), Avian influenza A (H5N1) virus, COVID-19, Influenza A virus(Flu A), Influenza B virus(Flu B), Respiratory syncytial virus(RSV), Adenovirus(ADV), M.Pneumoniae(MP), Parainfluenza virus 1/3(PIV1/3) and Parainfluenza virus 2(PIV 2) antigen in human nasal swab samples.

PRINCIPLE

This kit uses the double antibody-sandwich method to detect antigens. When an appropriate amount of specimen is added to the specimen well(s) of the test device, the specimen will move forward along the test device. If the specimen contains an antigen, the antigen binds to the antibody labeled with colloidal gold on the binding pad, and the immune complex forms a sandwich complex with another coated antibody which was coated on the test line, a visible colored line will show up, which indicates that the antigen is positive. The test device also contains a quality control line, regardless of whether there is a test line, the red quality control line should appear. If the quality control line does not appear, it indicates that the test result is invalid and need to do the test again.

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	OMIKRON	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.
- This test kit is intended for persons aged 18 and over. Users under the age of 18 should complete the test with supervision of an adult.
- 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.
- If the COVID-19 testis positive, there is a suspicion of a COVID-19 infection, contact your doctor/GP immediately or the local health department, follow local guidelines Self-isolate and perform a confirmatory PCR test.
- If the result of the ADV, RSV, MP, influenza A/B, PIV 1/3, PIV 2, H5N1,hMPV test is positive: There is currently the Suspected ADV, RSV, influenza A/B, MP, PIV 1/3, PIV 2, H5N1, hMPV infection and what to do next be undertaken according to local guidelines.
- Nasal bleeding should be avoided during sampling to minimize the occurrence of invalid results.
- If the H5N1 test is positive while the FluA test is negative, then the H5N1 result is considered invalid. First, check whether there is any nasal bleeding. If not, you may repeat the test. If the result remains the same, decide whether to seek medical attention based on your physical condition. If both the H5N1 and FluA tests are positive, then immediate hospital confirmation is required.
- 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 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

DIRECTIONS FOR USE

⚠ Allow the test device, sample extraction buffer to equilibrate to room temperature (15- 30°C) prior to testing, blowing the nose before taking a nasal swab .

Nasal Swab Specimen Collection :

BEFORE STARTING: Wash and sanitise your hands, then clean the nostrils.

1. Remove the swab from the package.

2. While gently rotating the swab, insert swab about 2-3cm into nostril until resistance is met at turbinates.

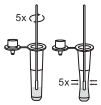
3. Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.

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 buffer.



2. Immerse the sampled swab into the sample extraction buffer to make the sample extraction buffer completely penetrate the swab, rotate and squeeze the swab 5 times, take out and discard the swab.

3. Insert the tube cap firmly on the sample extraction tube.Gently shake the extraction tube for about 10 seconds to make sure sample mix well with extraction buffer.

4. Transfer 2 drops of mixed sample into the test card vertically, start the timer. Read the result at 15 minutes. Don't interpret the result after 30 minutes.

**Read the result at 15 minutes. Result after 30 mins will not be valid.

⚠ Put used product components in the biohazard bag. Close the bag and put it in medical waste recycling bin.

INTERPRETATION OF RESULTS

POSITIVE (+)

- Flu A Positive: Two red bands appear in the Flu A/Flu B/COV detection zone. One is in the test zone (A), and the other is in the control zone (C).
- Flu B Positive: Two red bands appear in the Flu A/Flu B/COV detection zone. One is in the test zone (B), and the other is in the control zone (C).
- COVID-19 Positive: Two red bands appear in the Flu A/Flu B/COV detection zone. One is in the test zone (COV), and the other is in the control zone (C).
- Flu A/Flu B Positive: Three red bands appear in the Flu A/Flu B/COV detection zone. One is in the test zone (A), one is in the test zone (B), and the other is in the control zone (C).
- Flu A/COVID-19 Positive: Three red bands appear in the Flu A/Flu B/COV detection zone. One is in the test zone (A), one is in the test zone (COV), and the other is in the control zone (C).
- Flu B/COVID-19 Positive: Three red bands appear in the Flu A/Flu B/COV detection zone. One is in the test zone (B), one is in the test zone (COV), and the other is in the control zone (C).
- Flu A/Flu B/COVID-19 Positive: Four red bands appear in the Flu A/Flu B/COV detection zone. One is in the test zone (A), one is in the test zone (B), one is in the test zone (COV), and the other is in the control zone (C).
- RSV Positive: Two red bands appear in the RSV/ADV/MP detection zone. One is in the test zone (RSV), and the other is in the control zone (C).
- ADV Positive: Two red bands appear in the RSV/ADV/MP detection zone. One is in the test zone (ADV), and the other is in the control zone (C).
- MP Positive: Two red bands appear in the RSV/ADV/MP detection zone. One is in the test zone (MP), and the other is in the control zone (C).
- RSV/ADV Positive: Three red bands appear in the RSV/ADV/MP detection zone. One is in the test zone (RSV), one is in the test zone (ADV), and the other is in the control zone (C).
- RSV/MP Positive: Three red bands appear in the RSV/ADV/MP detection zone. One is in the test zone (RSV), one is in the test zone (MP), and the other is in the control zone (C).
- ADV/MP Positive: Three red bands appear in the RSV/ADV/MP detection zone. One is in the test zone (ADV), one is in the test zone (MP), and the other is in the control zone (C).
- RSV/ADV/MP Positive: Four red bands appear in the RSV/ADV/MP detection zone. One is in the test zone (RSV), one is in the test zone (ADV), one is in the test zone (MP), and the other is in the control zone (C).
- PIV1/3 Positive: Two red bands appear in the PIV1/3/PIV2 detection zone. One is in the test zone (1/3), and the other is in the control zone (C).
- PIV2 Positive: Two red bands appear in the PIV1/3/PIV2 detection zone. One is in the test zone (2), and the other is in the control zone (C).
- PIV1/3/PIV2 Positive: Three red bands appear in the PIV1/3/PIV2 detection zone. One is in the test zone (1/3), one is in the test zone (2), and the other is in the control zone (C).
- H5N1 Positive: Two red bands appear in the Flu A/Flu B/COV detection zone. One is in the test zone (A), and the other is in the control zone (C) and, Two red bands appear in the H5N1 detection zone. One is in the test zone (T), and the other is in the control zone (C).
- hMPV Positive: Two red bands appear in the HMPV detection zone. One is in the test zone (T), and the other is in the control zone (C).

**Note:The red line in the test line (T) can show different shades of color. However, even a very weak ribbon should be judged as a positive result during the specified observation period, regardless of the color of the ribbon.

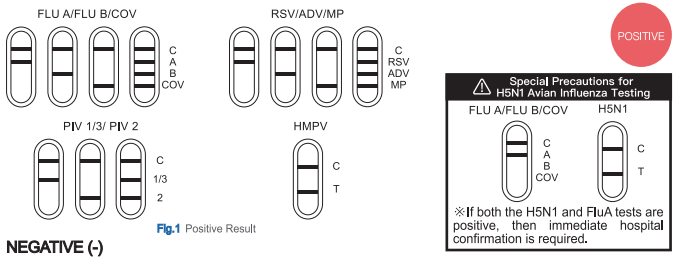


Fig.1 Positive Result

NEGATIVE (-)

If only quality control line C, test line T or test line A or test line B or test line COV or test line MP or test line ADV or test line RSV or test line PIV1/3 or test line PIV2 are colorless, it means that no antigen of corresponding pathogen is detected, and the result is negative.

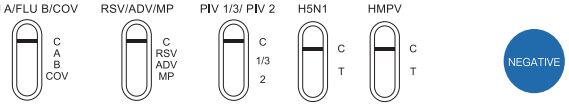


Fig.2 Negative Result

INVALID

If the quality control line C is not observed, it will be invalid regardless of whether there is test line T or test line A or test line B or test line COV or test line MP or test line ADV or test line RSV or test line PIV1/3 or test line PIV2, and the test shall be conducted again.

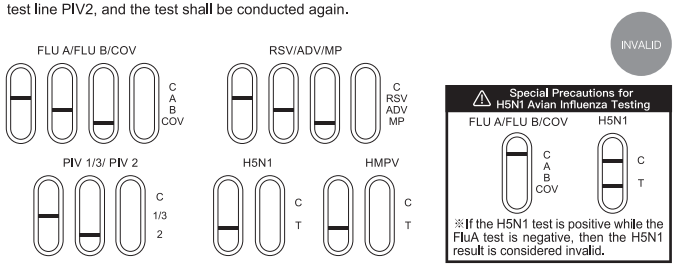


Fig.3 Invalid Result

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 hMPV, H5N1,COVID-19,Flu A & B, ADV, RSV, MP, PIV 1/3, PIV 2, 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

A total of 520 samples were collected in this study, of which 110 were positive and 410 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
COVID-19 Test		POS	NEG	Total	PPA	96.4%	90.8%	98.2%
	POS	106	1	107	NPA	99.8%	94.4%	99.9%
	NEG	4	409	413	Total compliance rate			99.0%
	TOTAL	110	410	520				

Sensitivity:96.4% (95% CI: 90.8% - 98.2%)
Specificity:99.8% (95% CI: 94.4% - 99.9%)
Accuracy: 99.0%

2.Influenza A test

A total of 305 samples were collected in this study, of which 105 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
Influenza A Test		POS	NEG	Total	PPA	>99.9%	96.47%	100%
	POS	105	0	105	NPA	>99.9%	98.12%	100%
	NEG	0	200	200	Total compliance rate			>99.9%
	TOTAL	105	200	305				

Sensitivity: >99.9% (95% CI: 96.47%-100%)
Specificity: >99.9% (95% CI:98.12%-100%)
Accuracy: >99.9%

3.Influenza B test

A total of 305 samples were collected in this study, of which 100 were positive and 205 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
Influenza B Test		POS	NEG	Total	PPA	>99.9%	96.30%	100%
	POS	100	0	100	NPA	>99.9%	98.16%	100%
	NEG	0	205	205	Total compliance rate			>99.9%
	TOTAL	100	205	305				

Sensitivity: >99.9% (95% CI: 96.30%-100%)
Specificity: >99.9% (95% CI:98.16%-100%)
Accuracy: >99.9%

4.RSV test

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
RSV Test		POS	NEG	Total	PPA	>99.9%	96.30%	100%
	POS	100	0	100	NPA	>99.9%	98.12%	100%
	NEG	0	200	200	Total compliance rate			>99.9%
	TOTAL	100	200	300				

Sensitivity: >99.9% (95% CI: 96.30%-100%)
Specificity: >99.9% (95% CI: 98.12%-100%)
Accuracy: >99.9%

5.ADV test

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
ADV Test		POS	NEG	Total	PPA	99.0%	94.55%	99.82%
	POS	99	0	99	NPA	>99.9%	98.12%	100%
	NEG	1	200	201	Total compliance rate			99.7%
	TOTAL	100	200	300				

Sensitivity: 99.0% (95% CI: 94.55%-99.82%)
Specificity: >99.9% (95% CI: 98.12%-100%)
Accuracy: 99.7%

6.MP test

A total of 206 samples were collected in this study, of which 58 were positive and 148 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
MP Test		POS	NEG	Total	PPA	98.3%	90.86%	99.70%
	POS	57	0	57	NPA	>99.9%	97.47%	100%
	NEG	1	148	149	Total compliance rate			99.5%
	TOTAL	58	148	206				

Sensitivity: 98.3% (95% CI: 90.86%-99.70%)
Specificity: >99.9% (95% CI: 97.47%-100%)
Accuracy: 99.5%

7.PIV 1/3 test

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
PIV 1/3 Test		POS	NEG	Total	PPA	>99.9%	96.30%	100%
	POS	100	0	100	NPA	>99.9%	98.12%	100%
	NEG	0	200	200	Total compliance rate			>99.9%
	TOTAL	100	200	300				

Sensitivity: >99.9% (95% CI: 96.30%-100%)
Specificity: >99.9% (95% CI: 98.12%-100%)
Accuracy: >99.9%

8.PIV 2 test

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
PIV 2 Test		POS	NEG	Total	PPA	99.0%	94.55%	99.82%
	POS	99	0	99	NPA	>99.9%	98.12%	100%
	NEG	1	200	201	Total compliance rate			99.7%
	TOTAL	100	200	300				

Sensitivity: 99.0% (95% CI: 94.55%-99.82%)
Specificity: >99.9% (95% CI: 98.12%-100%)
Accuracy: 99.7%

9.H5N1 test

A total of 108 samples were collected in this study, of which 32 were positive and 76 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
H5N1 Test		POS	NEG	Total	PPA	96.9%	84.26%	99.45%
	POS	31	0	31	NPA	>99.9%	95.19%	100%
	NEG	1	76	77	Total compliance rate			99.1%
	TOTAL	32	76	108				

Sensitivity: 96.9% (95% CI: 84.26%-99.45%)
Specificity: >99.9% (95% CI: 95.19%-100%)
Accuracy: 99.1%

10.hMPV test

A total of 262 samples were collected in this study, of which 62 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Reference PCR Assay							95% Wilson Score CI	
							LCI	UCI
hMPV Test		POS	NEG	Total	PPA	96.8%	88.98%	99.11%
	POS	60	0	60	NPA	>99.9%	98.12%	100%
	NEG	2	200	202	Total compliance rate			99.2%
	TOTAL	62	200	262				

Sensitivity: 96.8% (95% CI: 88.98%-99.11%)
Specificity: >99.9% (95% CI: 98.12%-100%)
Accuracy: 99.2%

Limit of detection (LOD)

Category	LOD
Flu A	$1*10^4$CFU/mL
Flu B	$1*10^4$CFU/mL
COVID-19	80 $TCID_{50}$/mL
RSV-A	$1.05*10^4$ $TCID_{50}$/mL
RSV-B	$1.2*10^4$ $TCID_{50}$/mL
ADV	200 $TCID_{50}$/mL
MP	$1*10^3$CFU/mL
PIV1/3	50ng/mL
PIV2	20ng/mL
H5N1	$4.88*10^3$ EID_{50}/mL
hMPV	$1*10^2$ $TCID_{50}$/mL

Cross Reaction

The cross-reactivity of this reagent is evaluated by testing a group of related pathogens, high-prevalence disease pathogens, and normal or pathogenic flora. The results prove that the product has no cross-reactivity,including Staphylococcus aureus、Streptococcus pneumoniae、Measles virus、Mumps virus、Bordetella pertussis、EB virus、Human enterovirus A (CA16)、Rhinovirus、Rotavirus、Norovirus、Chlamydia pneumoniae.Moreover, there is no cross-reactivity among the ten viruses tested by this kit.

Interfering Substances Reaction

Test results below the corresponding concentrations of substances listed in the table will not affect the performance of this reagent, and no interference reactions will occur.

Name	Concentration
Sodium Chloride	40 mg/mL
Beclomethasone	40 mg/mL
Dexamethasone	40 mg/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
REF	Catalogue number	Σ	Contains Sufficient For <n> Tests
	This Way Up		Do Not Use If Package Is Damaged
	Keep Away From Sunlight		Keep Dry
	Keep out of reach of children		Biological Hazard

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TEN RESPIRATORY PATHOGENS ANTIGEN TEST KIT

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