JOY TEST

No.IFU-RP12Ag-NNP-01,Ver.A/0

CE

Twelve Respiratory Pathogens Antigen Test Kit

For professional use only

[Intended use]

This product is used for the qualitative detection of COVID-19 influenza A, influenza B, respiratory syncytial virus (RSV), adenovirus, Mycoplasma Pneumoniae, parainfluenza virus, human metapneumovirus, Rhinovirus, Streptococcus pneumoniae, Legionella pneumophila, B. pertussis in human nasal swabs, nasopharyngeal (NP) swabs.

[Summary]

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus 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 main Manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. Once infected with the COVID-19 virus, you may be hospitalized and some complications may occur.

Influenza, usually called "flu", is an acute respiratory infectious disease caused by influenza viruses. It is highly contagious and is spread mainly through coughing and sneezing. It usually breaks out in spring and winter. Divided into influenza A virus, influenza B virus and influenza C virus. Influenza A virus has strong variability, followed by influenza B virus, and influenza C virus is very stable, so influenza A virus is more serious and prevalent than influenza B virus.

Respiratory syncytial virus (RSV) is a common, and very contagious, virus that infects the respiratory tract of most children before their second birthday. Nearly half of all children become infected by RSV in their first year of life. It is also the major viral cause of nosocomial illness in children already hospitalized for other reasons. In children hospitalized with RSV infection, it is believed to be the most common viral cause of death in children younger than 5 years, particularly in children younger than one year. RSV infection can cause cold-like symptoms, including a cough and runny nose, which usually last 1 to 2 weeks. Respiratory syncytial virus spreads through the air, like after a cough or a sneeze, and through direct contact like touching. People are typically infected with RSV for the first time as an infant or toddler and nearly all children are infected before their second birthday. However, repeat infections may occur throughout life, and people of any age can be infected. Infections in healthy children and adults are generally less severe than among infants and older adults with certain medical conditions.

Although a wide variety of viral agents are capable of causing lower respiratory tract infections in children and adults, influenza A & B; respiratory syncytial virus (RSV); parainfluenza viruses; and adenovirus are the most common. however, depending on the infecting serotype, they may also cause various other illnesses, such as gastroenteritis, conjunctivitis, cystitis and rash illness. Symptoms of respiratory illness caused by Adenovirus infection range from the common cold syndrome to pneumonia, croup and bronchitis. Patients with compromised immune systems are especially susceptible to severe complications of Adenovirus infection. Adenovirus is transmitted by direct contact, fecal-oral transmission and occasionally waterborne transmission. Some types are capable of establishing persistent asymptomatic infections in tonsils, adenoids and intestines of infected hosts and shedding can occur for months or years.

Mycoplasma pneumoniae（MP） is a type of bacteria that lacks a cell wall, making it unique among bacterial pathogens. It is a common cause of respiratory infections, particularly atypical pneumonia, often referred to as "walking pneumonia." This pathogen primarily affects the upper and lower respiratory tract, leading to symptoms such as fever, cough, sore throat, and fatigue. Infections caused by Mycoplasma pneumoniae are typically mild but can occasionally result in more severe complications, especially in individuals with weakened immune systems. It spreads through respiratory droplets, making it highly contagious in close-contact settings like schools and households.

Parainfluenza viruses (PIV) are common respiratory pathogens that belong to the Paramyxoviridae family. They are a leading cause of respiratory infections, particularly in infants, young children, and immunocompromised individuals. These viruses are responsible for a range of illnesses, from mild upper respiratory tract infections, such as the common cold, to more severe lower respiratory tract infections, including croup, bronchiolitis, and pneumonia. Parainfluenza viruses spread through respiratory droplets or direct contact with contaminated surfaces, making them highly contagious. While infections can occur year-round, they often peak in the fall and spring. There is currently no specific antiviral treatment for parainfluenza virus infections, and management typically focuses on relieving symptoms. Preventive measures, such as good hygiene practices and avoiding close contact with infected individuals, are essential to reduce transmission.

Human metapneumovirus (hMPV) was first reported in 2001 in the Netherlands and since then has been found to be distributed world wide and is associated with a significant proportion of the respiratory infections in early infancy and childhood, but is present in all age groups. It is RNA virus that belongs to the Metapneumovirus genus within the Pneumovirinae subfamily of the Paramyxoviridae family, which can cause respiratory infection. hMPV infection is a typical respiratory infection in infants. hMPV, like other common respiratory viruses including RSV and Influenza, causes seasonal epidemics centred around the winter months, and symptoms are very similar to those experienced by patients infected with RSV, including most commonly fever with upper respiratory symptoms such as cough and nasal congestion. However, hMPV has also been associated with more severe illness and lower respiratory tract symptoms such as pneumonia and bronchitis. hMPV has also been linked with an exacerbation of asthma and wheezing in infected individuals, although there is some evidence that it is not as common a cause of wheezing as RSV and rhinoviruses. It has been shown that hMPV is associated with co-infections, particularly with respect to RSV.

Rhinovirus (RhV) is a small, non-enveloped, single-stranded RNA virus belonging to the Picornaviridae family. It is the most common viral agent causing the common cold, responsible for approximately 30–50% of upper respiratory infections. RhV thrives in the nasal passages and throat, leading to symptoms such as runny nose, sneezing, sore throat, and mild cough.With over 160 known serotypes, RhV exhibits high genetic diversity, making long-term immunity difficult to develop. It spreads via respiratory droplets or direct contact (e.g., touching contaminated surfaces). While infections are usually mild and self-limiting, RhV can exacerbate asthma, chronic obstructive pulmonary disease (COPD), or lead to secondary bacterial infections in vulnerable individuals.

Streptococcus pneumoniae (Sp)is a Gram-positive, lancet-shaped bacterium that commonly colonizes the human nasopharynx asymptomatically. As a leading cause ofcommunity-acquired pneumonia, it also triggers invasive diseases like meningitis, bacteremia, and otitis media, particularly in young children, elderly, and immunocompromised individuals.

Encapsulated with over 90 serotypes (classified by polysaccharide capsules), its virulence factors include pneumolysin toxin and evasion of phagocytosis. Transmission occurs via respiratory droplets.

Legionella pneumophilais (Lp)a Gram-negative, aerobic bacillus and the primary pathogen responsible for Legionnaires' disease, a potentially fatal form of pneumonia. This waterborne bacterium thrives in warm environments (20-45°C) and commonly colonizes man-made water systems such as cooling towers, plumbing systems, and hot tubs. Transmission occurs through inhalation of contaminated aerosols. The bacteria evade host defenses by replicating within alveolar macrophages using a specialized type IV secretion system. Clinical manifestations range from mild Pontiac fever to severe pneumonia with multisystem complications.

Whooping cough, also known as pertussis, is a highly contagious respiratory tract infection caused by the bacterium Bordetella pertussis(B.P). It is characterized by severe, uncontrollable coughing fits that often end with a high-pitched "whooping" sound as the patient gasps for air. This violent coughing can make it difficult to breathe, eat, or sleep. While it can affect people of all ages, it is most dangerous for infants and young children who may not yet be fully vaccinated, potentially leading to life-threatening complications like pneumonia, seizures, and apnea.

The gold standard method for laboratory diagnosis is the virus isolation and culture method, while the long cycle time for cell culture identification

seriously affects the timely clinical guidance of patient medication, and the method is limited in clinical application. Compared with the cell culture method, reverse transcription-polymerase chain reaction (RT-PCR) has higher sensitivity, but the cost of RT-PCR method is higher, the experiment time takes 4-6 hours, and the experiment operation is more professional , So the field application is restricted. This product is used for the qualitative detection of COVID-19 influenza A, influenza B, respiratory syncytial virus (RSV), adenovirus, Mycoplasma Pneumoniae, parainfluenza virus, human metapneumo virus, Rhinovirus, Streptococcus pneumoniae, Legionella pneumophila,in human nasal swabs, nasopharyngeal (NP) swabs.

[Test 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.

[Warnings and Precautions]

1. For *in vitro* diagnostic use.
2. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
3. The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.
4. Guard against moisture, do not open the aluminum platinum bag before it is ready for testing. Do not use it if the aluminum foil bag is damaged or the test device is damp.
5. Please use it within the validity period.
6. Balance all reagents and specimens to room temperature (15 ~ 30 ℃) before use.
7. Do not replace the components in this kit with components in other kits.
8. Do not dilute the specimen when testing, otherwise you may get inaccurate results.
9. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezing conditions.
10. The test methods and results must be interpreted in strict accordance with this specification.
11. Negative results may occur if the antigen titer in the specimen falls below the minimum detection limit of this kit.
12. Do not eat, drink or smoke in the area where the specimens or kits are handled. Wash hands thoroughly after finishing the tests.
13. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.
14. Do not mix and interchange different specimens.

[Materials and Components]

Materials provided

1) Sterilized Swab
2) Antigen extraction tube with Extraction Reagent
3) Test device
4) Instruction
5) Tube Rack (Optional)

Materials required but not provided

Timer.

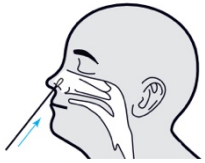
[Storage conditions & period of validity]

1. The kit should be stored at 2-30 ℃ until the expiry date printed on the sealed pouch.
2. After the foil pouch is unsealed, the test device should be used as soon as possible within one hour.
3. The test device should be kept away from direct sunlight, moisture and heat.
4. Do not freeze the test kit.

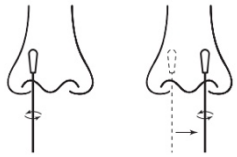
[Specimen Collection]

Option 1: Anterior Nasal Swab Sample:

1. Let the patient's head relax naturally, take out the swab. Carefully insert the swab into the patient's nostril,the swab tip should be inserted up to 2-3 c m until resistance is met.



2. Roll the swab 5 times along the mucosa inside the nostril to ensure the mucus and cells are collected. Using the same swab, repeat this process for the other nostril to ensure an adequate specimen is collected.



3.Withdraw the swab from the nasal cavity.

Option 2:Nasopharyngeal (NP) swab sample:

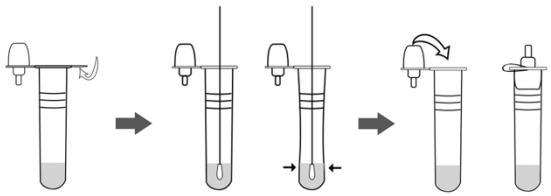
Let the patient's head relax naturally, and slowly rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping. Using the same swab, wipe the other nostril in the same way.

[Sample Transport and Storage]

After Swab specimens were collected, swab can be stored in extraction reagent provided with the kit. Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Specimen collected may be stored at 2-8℃for no more than 24 hours; Store at -70 ℃ for a long time, but avoid repeated freeze-thaw cycles.

[Specimen Preparation]

1. Tear off the sealing film on the antigen extraction tube.
2. Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. so as to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
4. Insert a dropper tip into the extraction tube tightly.



[Test Procedure]

Read the instructions carefully before use and bring test device, extraction reagent and specimens were restored to room temperature.

1. Open the package and take out the test device.
2. Hold the extraction tube vertically and add two drops of the test specimens into specimen well (s). Start the timer.
3. Read results at 15 minutes. Do not read results after 30 minutes.

[Interpretation of test results]

Positive result:

(1) 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).

(2) 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).

(3)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).

(4) 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).

(5) 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).

(6) 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).

(7) 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).

(8) RSV Positive: Two red bands appear in the RSV/ADV/HMPV detection zone. One is in the test zone (RSV), and the other is in the control zone (C).

(9) ADV Positive: Two red bands appear in the RSV/ADV/HMPV detection zone. One is in the test zone (ADV), and the other is in the control zone (C).

(10) HMPV Positive: Two red bands appear in the RSV/ADV/HMPV detection zone. One is in the test zone (HMPV), and the other is in the control zone (C).

(11) RSV/ADV Positive: Three red bands appear in the RSV/ADV/HMPV 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).

(12) RSV/HMPV Positive: Three red bands appear in the RSV/ADV/HMPV detection zone. One is in the test zone (RSV), one is in the test zone (HMPV), and the other is in the control zone (C).

(13) ADV/HMPV Positive: Three red bands appear in the RSV/ADV/HMPV detection zone. One is in the test zone (ADV), one is in the test zone (HMPV), and the other is in the control zone (C).

(14) RSV/ADV/HMPV Positive: Four red bands appear in the RSV/ADV/HMPV detection zone. One is in the test zone (RSV), one is in the test zone (ADV), one is in the test zone (HMPV), and the other is in the control zone (C).

(15) PIV Positive: Two red bands appear in the MP/PIV detection zone. One is in the test zone (PIV), and the other is in the control zone (C).

(16) MP Positive: Two red bands appear in the MP/PIV detection zone. One is in the test zone (MP), and the other is in the control zone (C).

(17)PIV/MP Positive:Three red bands appear in the MP/PIV detection zone. One is in the test zone (PIV), one is in the test zone (MP), and the other is in the control zone (C).

(18)RhV Positive:Two red bands appear in the RhV/SP/LP detection zone. One is in the test zone (RhV), and the other is in the control zone (C).

(19)SP Positive:Two red bands appear in the RhV/SP/LP detection zone. One is in the test zone (SP), and the other is in the control zone (C).

(20)LP Positive:Two red bands appear in the RhV/SP/LP detection zone. One is in the test zone (LP), and the other is in the control zone (C).

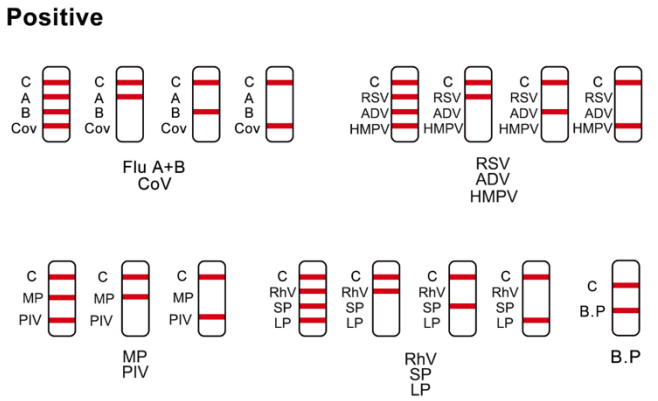
(21)RhV/SP Positive:Three red bands appear in the RhV/SP/LP detection zone. One is in the test zone (RhV), one is in the test zone (SP), and the other is in the control zone (C).

(22)RhV/LP Positive:Three red bands appear in the RhV/SP/LP detection zone. One is in the test zone (RhV), one is in the test zone (LP), and the other is in the control zone (C).

(23)SP/LP Positive:Three red bands appear in the RhV/SP/LP detection zone. One is in the test zone (SP), one is in the test zone (LP), and the other is in the control zone (C).

(24)RhV/SP/LP Positive:Four red bands appear in the RhV/SP/LP detection zone. One is in the test zone (RhV), one is in the test zone (SP), one is in the test zone (LP), and the other is in the control zone (C).

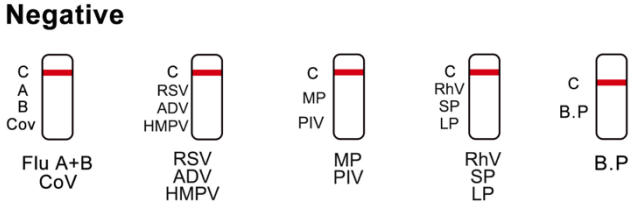
(25)B.P Positive:Two red bands appear in the B.P detection zone. One is in the test zone (B.P), and the other is in the control zone (C).



Note: The red line in the test line 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.

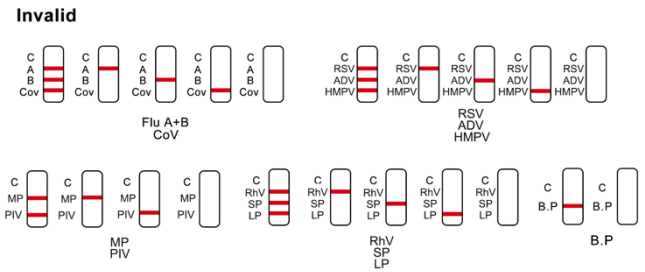
Negative result:

If only quality control line C is colored, test line A or test line B or test line COV or test line HMPV or test line ADV or test line RSV or test line PIV or test line MP or test line RhV or test line SP or test line LP or test line BP are colorless, it means that no antigen of corresponding pathogen is detected, and the result is negative.



Invalid result:

If the quality control line C is not observed, it will be invalid regardless of whether there is test line A or test line B or test line COV or test line HMPV or test line ADV or test line RSV or test line PIV or test line MP or test line RhV or test line SP or test line LP or test line BP, and the test shall be conducted again.



[Quality Control]

A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume.

[Limitations of inspection methods]

1. This product is used for qualitative testing only and cannot indicate the level of antigen in the specimen.
2. This test kit is only used to detect human nasal swabs, nasopharyngeal (NP) swabs extracts. The results of other specimens may be wrong.
3. This test kit is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.
4. Diagnosis and treatment can not only rely on this test result. Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.
5. The strength of the test line is not linearly related to the antibody titre in the specimen.

[Performance index]

1. Physical characters

1.1 Appearance

The test should be clean and complete, no burr, no damage and non-pollution. The shell of the test cassette should be flat, the upper and lower covers should be evenly closed, and there should be no obvious gap. The inner test strip should be firmly attached without waggle. The extraction reagent should be free of foreign matter.

1.2 Size

The size of the inner strip should not be less than 2.5mm.

1.3 Liquid migration speed

It should not be less than 10mm/min.

2. Sensitivity

2.1.Limit of detection (LOD)

Category		LOD
Influenza A	LiaoNing/183/2007(HINI)	2.2 x 10^3 $TCID_{50}$/mL
Influenza A	A/Victoriw3/75	1.16 x10^2 $TCID_{50}$/mL
Infuenza A	A/HongKong/8/68	2.58 x10^4 $TCID_{50}$/mL
Infuenza B	Jiang Xi/32/2000/	2.9 x10^2 $TCID_{50}$/mL
Infuenza B	B/1704	6.8 x10^2 $TCID_{50}$/mL
COVID-19		80 $TCID_{50}$/mL
RSV		10 ng/ml
ADV		10 ng/ml
MP		1*10^3CFU/mL
PIV		20ng/mL
HMPV		1*10^2 $TCID_{50}$/mL
RhV		10ng/mL
SP		1*10^3CFU/mL
LP		1*10^3CFU/mL
B.P		1*10^3CFU/mL

3. Specificity

3.1 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、Measles virus、Mumps virus、Bordetella pertussis、EB virus、Human enterovirus CA16、Chlamydia pneumoniae.Moreover, there is no cross-reactivity among the twelve viruses tested by this kit.

Pathogen Name	Concentration
Staphylococcus aureus	1.0*10^6 copies/mL
Measles virus	1.0*10^6 copies/mL
Mumps virus	1.0*10^6 copies/mL
Bordetella pertussis	1.0*10^6 copies/mL
EB virus	1.0*10^6 copies/mL
Human enterovirus CA16	1.0*10^6 copies/mL
Chlamydia pneumoniae	1.0*10^6 copies/mL

3.2 Interfering substances

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

4. Clinical performance

4.1 COVID-19 Rapid 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:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE 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%

4.2 Influenza A Rapid 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:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE 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%

4.3 Influenza B Rapid 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:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE 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%

4.4 RSV Rapid 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:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE 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%

4.5 ADV Rapid 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:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE ADV Test		POS	NEG	Total	PPA	99.00%	94.55%	99.82%
	POS	99	0	99	NPA	＞99.9%	98.12%	100%
	NEG	1	200	201	Total compliance rate			99.67%
	TOTAL	100	200	300				

Sensitivity: 99.00% (95% CI: 94.55%-99.82%)
Specificity:＞99.9% (95% CI: 98.12%-100%)
Accuracy: 99.67%

4.6 MP Rapid 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:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE MP Test		POS	NEG	Total	PPA	98.28%	90.86%	99.70%
	POS	57	0	57	NPA	＞99.9%	97.47%	100%
	NEG	1	148	149	Total compliance rate			99.51%
	TOTAL	58	148	206				

Sensitivity: 98.28% (95% CI: 90.86%-99.70%)
Specificity:＞99.9% (95% CI: 97.47%-100%)
Accuracy: 99.51%

4.7 PIV Rapid 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:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE PIV 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%

4.8 HMPV Rapid 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:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE HMPV Test		POS	NEG	Total	PPA	96.77%	88.98%	99.11%
	POS	60	0	60	NPA	＞99.9%	98.12%	100%
	NEG	2	200	202	Total compliance rate			99.24%
	TOTAL	62	200	262				

Sensitivity: 96.77% (95% CI: 88.98%-99.11%)
Specificity:＞99.9% (95% CI: 98.12%-100%)
Accuracy: 99.24%

4.9 Bordetella pertussis Rapid Test:

A total of 348 samples were collected in this study, of which 113 were positive and 235 were negative. The statistics of the study results are shown in the following table:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE BP Test		POS	NEG	Total	PPA	98.23%	93.78%	99.51%
	POS	111	0	111	NPA	＞99.9%	98.39%	100%
	NEG	2	235	237	Total compliance rate			99.43%
	TOTAL	113	235	348				

Sensitivity: 98.23% (95% CI: 93.78%-99.51%)
Specificity:＞99.9% (95% CI: 98.39%-100%)
Accuracy: 99.43%

4.10 RhV Rapid Test:

A total of 312 samples were collected in this study, of which 105 were positive and 207 were negative. The statistics of the study results are shown in the following table:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE RhV Test		POS	NEG	Total	PPA	96.19%	90.61%	98.51%
	POS	101	0	101	NPA	＞99.9%	98.18%	100%
	NEG	4	207	211	Total compliance rate			98.72%
	TOTAL	105	207	312				

Sensitivity: 96.19% (95% CI: 90.61%-98.51%)
Specificity:＞99.9% (95% CI: 98.18%-100%)
Accuracy: 98.72%

4.11 SP Rapid 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:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE SP Test		POS	NEG	Total	PPA	96.00%	90.16%	98.43%
	POS	96	1	97	NPA	99.50%	97.22%	99.91%
	NEG	4	199	203	Total compliance rate			98.33%
	TOTAL	100	200	300				

Sensitivity: 96.00% (95% CI: 90.16%-98.43%)
Specificity:99.50% (95% CI: 97.22%-99.91%)
Accuracy: 98.33%

4.12 LP Rapid Test:

A total of 307 samples were collected in this study, of which 106 were positive and 201 were negative. The statistics of the study results are shown in the following table:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
DEEPBLUE LP Test		POS	NEG	Total	PPA	98.11%	93.38%	99.48%
	POS	104	0	104	NPA	＞99.9%	98.12%	100%
	NEG	2	201	203	Total compliance rate			99.35%
	TOTAL	106	201	307				

Sensitivity: 98.11% (95% CI: 93.38%-99.48%)
Specificity:＞99.9% (95% CI: 98.12%-100%)
Accuracy: 99.35%

[Instruction of Symbols]

CE	CE mark	LOT	Batch number
	Consult instructions for use	IVD	In vitro diagnostic *medical device*
	Do not re-use		Date of manufacture
	Storage temperature		Contains sufficient for <n> tests
	Manufacturer		Use before the date
EC REP	Authorized Representative in European Community		Keep dry
	Keep away from sunlight		Do not use if package is damaged and consult instructions for use

Revision Date:2025-08-18

Czech Original Products s.r.o. - JOYMED.cz
Koulova 6, Praha 6, 160 00 - CZ
IČ: 08595771, DIČ: CZ08595771
+420 608 284 065 obchod@joymed.cz

Specification	REF
1 piece per box	RP1211NNP-1
2 pieces per box	RP1211NNP-2
3 pieces per box	RP1211NNP-3
5 pieces per box	RP1211NNP-5
10 pieces per box	RP1211NNP-10
15 pieces per box	RP1211NNP-15
20 pieces per box	RP1211NNP-20
25 pieces per box	RP1211NNP-25

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA
E-mail:sales@dbluemedical.com

EC REP

Medunion S.L.
CALLE TAPIOLES, 33, 2- 1,
08004 - Barcelona BARCELONA Cataluña