

Influenza A/B+COVID-19/RSV Combo Ag Test

Model: Multi-panel
Specimen: Nasal swab specimen

INTENDED USE

Influenza A/B+COVID-19/RSV Combo Ag Test is an in vitro immunochromatographic assay for the qualitative and differential detection of nucleocapsid protein antigen from influenza A (including the subtype H1N1), influenza B, respiratory syncytial virus and/or SARS-CoV-2 in nasal swab specimens from individuals with or without symptoms or other epidemiological reasons to suspect Flu A/B, RSV and/or COVID-19 infections.

It is intended to aid in the rapid diagnosis of influenza A, influenza B, respiratory syncytial virus and/or SARS-CoV-2 infections. This test is intended for non-prescription home use with self-collected nasal swab specimens from individuals aged 14 years and older with symptoms of Flu A/B & RSV/COVID-19 within the first 7 days of symptoms onset. The test is also intended for adult-collected nasal samples from individuals aged 2 years or older with signs and symptoms of Flu A/B & RSV/COVID-19 within the first 7 days of symptoms onset. This test is intended for non-prescription home use with self-collected direct nasal swab specimens from individuals aged 14 years and older, or adult-collected nasal samples from individuals aged 2 years or older with, or without symptoms or other epidemiological reasons to suspect Flu A/B & RSV/COVID-19. In individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 infections and without known exposure to COVID-19, more false positive results may occur. Testing of individuals without symptoms should be limited to contacts of confirmed or probable cases or to other epidemiological reasons to suspect a COVID-19 infection and should be followed by additional confirmatory testing with a molecular test.

This test provides only a preliminary test result. Therefore, any reactive specimen with the Influenza A/B+COVID-19/RSV Combo Ag Test must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Influenza is a highly contagious, acute viral infection of the respiratory tract with symptoms such as headache, chills, dry cough, body aches or fever. It is a communicable disease that is easily transmitted through aerosolized droplets containing live virus from coughing and sneezing. The causative agents of the disease are immunologically diverse single strand RNA viruses known as influenza viruses. Influenza type A viruses are typically more prevalent than influenza type B viruses and are associated with most sensitive influenza epidemics, while influenza type B infections are usually milder. Diagnosis is difficult because the initial symptoms are similar to those caused by other infectious agents. Accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Rapid and accurate diagnosis of influenza viral infection can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe appropriate antiviral medications.

Respiratory syncytial virus is an RNA virus belonging to the paramyxoviridae family. The disease is spread by airborne droplets and close contact. It is more common in newborns and infants less than 6 months old. The incubation period is 3 ~ 7 days. Infants and young children have more severe symptoms, including high fever, rhinitis, pharyngitis and laryngitis, followed by bronchiolitis and pneumonia. A few sick children can be complicated with otitis media, pleurisy and myocarditis, etc. Upper respiratory tract infection is the main symptom of infection in adults and elder children.

CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. Evidence suggests transmission via fecal-oral route. 7 kinds of HCoV are caused human's respiratory diseases are found by now: HCoV-229E, CoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU, MERS-CoV and COVID-19 which are the serious pathogens for human's respiratory diseases. Its clinical manifestation are fever, enervate and systemic symptom, with dry cough, difficult breathing etc. and it may aggravate to severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolic disorders etc and even life threatening rapidly.

PRINCIPLES

The Flu A/B Antigen Test strip uses mouse anti-influenza A monoclonal antibody (T1), mouse anti-influenza B monoclonal antibody (T2), and goat anti-mouse IgG polyclonal antibodies (C) that are respectively immobilized on a nitrocellulose membrane. It uses colloidal gold to label mouse anti-influenza A monoclonal antibody and mouse anti-influenza B monoclonal antibody. Using nano-colloidal gold technology and applying highly specific antibody-antigen reaction and immunochromatographic analysis technology principle. When testing, the Influenza type A viruses antigen in the sample combined with the colloidal gold-labeled mouse anti-influenza A monoclonal antibody to form a complex, which was then combined with the mouse anti-influenza A monoclonal antibody coated in the test line T1 during chromatography, at this time there is one red line in the T1 area. The Influenza type B viruses antigen in the sample combined with the colloidal gold-labeled mouse anti-influenza B monoclonal antibody to form a complex, which was then combined with the mouse anti-influenza B monoclonal antibody

coated in the test line T2 during chromatography, at this time there is one red line in the T2 area. When the samples do not contain Influenza type A and B viruses antigens, there is no red colored lines in the T1 and T2 areas. Regardless of the presence of Influenza type A or B viruses antigens in the sample, a red line will always form in the quality control area (C). The red line appears in the quality control area (C) serves as a verification 1. that sufficient volume of sample is added 2. that proper flow is obtained 3. and as a quality control for the reagents. The COVID-19/RSV Antigen Test strip uses mouse anti-COVID-19 monoclonal antibody (T2), mouse anti-RSV monoclonal antibody (T1) and goat anti-mouse IgG polyclonal antibodies (C) that are respectively immobilized on a nitrocellulose membrane. It uses colloidal gold to label mouse anti-COVID-19 monoclonal antibody, mouse anti-RSV monoclonal antibody. Using nano-colloidal gold technology and applying highly specific antibody-antigen reaction and immunochromatographic analysis technology principle. When testing, the COVID-19 antigen in the sample combined with the colloidal gold-labeled mouse anti-COVID-19 monoclonal antibody to form a complex, which was then combined with the mouse anti-COVID-19 monoclonal antibody coated in the test line T2 during chromatography, at this time there is one red line in the T2 area. The RSV antigen in the sample combined with the colloidal gold-labeled RSV monoclonal antibody to form a complex, which was then combined with the mouse anti-RSV monoclonal antibody coated in the test line T1 during chromatography, at this time there is one red line in the T1 area. When the samples do not contain COVID-19 and RSV antigens, there is no red colored lines in the T1 and T2 areas. Regardless of the presence of COVID-19 or RSV viruses antigens in the sample, a red line will always form in the quality control area (C). The red line appears in the quality control area (C) serves as a verification 1. that sufficient volume of sample is added 2. that proper flow is obtained 3. and as a quality control for the reagents.

MATERIALS PROVIDED

The Influenza A/B+COVID-19/RSV Combo Ag Test contains the following items to perform the assay:

1. Test cassette
2. Instruction for use
3. Sample collection tube containing processing solution
4. Sampling swab
5. Collection bag (Optional)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNING AND PRECAUTIONS

1. Read instructions for use carefully before performing this test.
2. For in vitro diagnostic use only.
3. Do not use the test cassette beyond the expiration date.
4. The test cassette should remain in the sealed pouch until use. Do not use the test cassette if the pouch is damaged or the seal is broken.
5. Do not reuse the cassette and swab.
6. Do not mix and interchange different specimens.
7. You need to use the swab provided in the kit for sampling.
8. The testing process must follow SPECIMEN PREPARATION and TEST PROCEDURE.
9. After the test, collect and put used product components in the collection bag. Close the bag and put it in another plastic bag. Dispose of the bag with household garbage. Or collect and process according to the requirements of the local epidemic prevention department.
10. Do not touch the swab head when handling the swab.
11. Insufficient sampling or wrong sampling process may lead to wrong results.
12. Keep test kit and materials out of the reach of children and pets before and after use.
13. Wear safety mask or other face covering when collecting swabs from children or others.

STORAGE AND STABILITY

Storage: store at 2~30 °C.

Shelf life: 24 months.

The opened cassette should be used within 1 hour.

SPECIMEN PREPARATION

1. Cleaning preparation before test

Wash or sanitize your hands, and dry completely.



2. Sample collection and processing

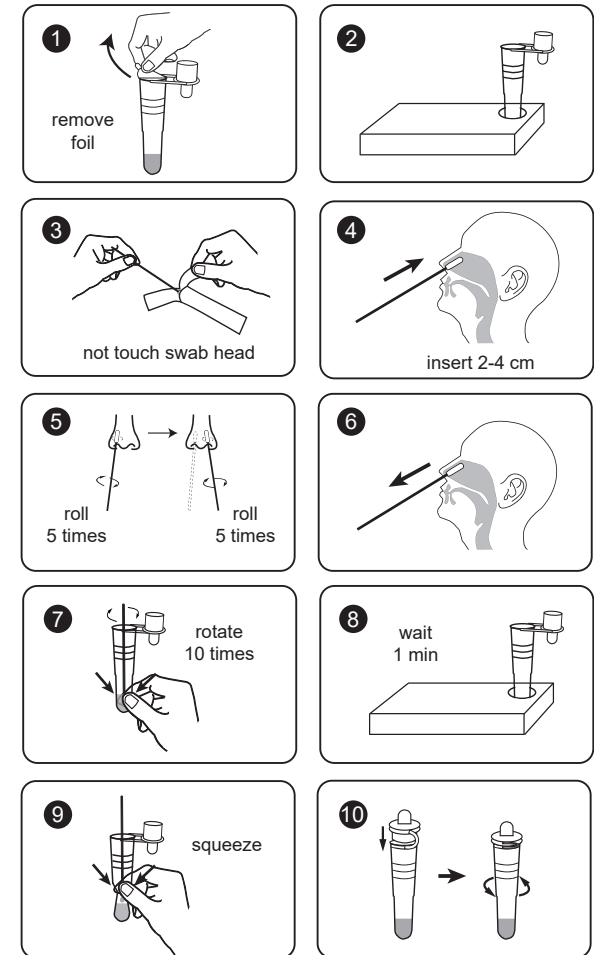
NOTE: The collected swab samples should be processed and tested immediately.

NOTE: If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

NOTE: Failure to swab properly may cause false negative results.

NOTE: Please wash your hands before and after the test.

NOTE: Do not touch the tip (specimen collection area) of the swab.

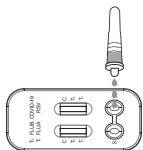


- 1) Remove the foil from the top of the sample collection tube.
- 2) Place the tube in the tube rack or the hole on box backside.
- 3) Remove a sampling swab from the pouch.
- 4) Using the sterile swab provided in the kit, carefully insert the swab into one nostril.
- 5) The swab tip should be inserted up to 2-4 cm until resistance is met. Roll the swab 5 times in a circular motion around the inside wall to ensure that both mucus and cells are collected. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
- 6) Withdraw the swab from the nasal cavity.
- 7) The specimen is now ready for preparation using the extraction buffer provided in the test kit. Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times while pressing the head against the bottom and side of the collection tube.
- 8) Leave the swab in the collection tube for 1 minute.
- 9) Rotate and squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab.
- 10) Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.

NOTE:

- ① Please use swab for specimen collection.
- ② It is highly recommended to collect specimen with wearing a pair of safety gloves to avoid contamination.
- ③ Collect sample as soon as after onset of symptoms.
- ④ It is recommended to treat the sample immediately after collection.

TEST PROCEDURE



Read the instructions first prior to testing. Bring the pouched test to room temperature prior to testing. Do not open the pouch until ready to begin testing.

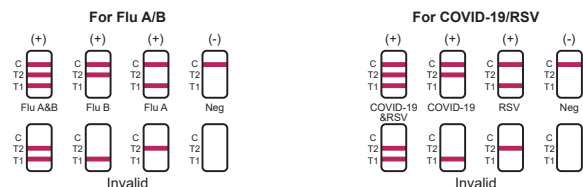
1. Remove the test from the sealed pouch. Lay it on a flat, clean and dry surface.
2. Reverse the sample collection tube, and add 3 drops of test sample by squeezing the collection solution tube into each of the sample well.
3. Read results at 15 minutes.

NOTE:

The test cassette should not be moved or lifted during the test to prevent inaccurate results. The test is intended to be read at 15 minutes. If the test is read before 10 minutes or is read more than 30 minutes, results may be inaccurate (false negative, false positive, or invalid) and the test should be repeated.

Collect all the used package components and sealed in collection bag: including swab, test cassette and assay diluent bottle. Discard waste bag in accordance with local legislation.

INTERPRETATION OF RESULTS



For Flu A/B Antigen Test

1.POSITIVE:

1.1 Flu A Positive:

The presence of two lines as control line (C) and T1 test line within the result window indicates a positive result for Influenza A viral antigen.

1.2 Flu B Positive:

The presence of two lines as control line (C) and T2 test line within the result window indicates a positive result for Influenza B viral antigen.

1.3 Flu A+B Positive:

The presence of three lines as control line (C), T1 test line and T2 test line within the result window indicates a positive result for Influenza A and Influenza B viral antigen.

2.NEGATIVE:

The presence of only control band (C) within the result window indicates a negative result.

3.INVALID:

If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test. If the problem persists, please stop using the product and contact with the test distributor.

For COVID-19/RSV Antigen Test

1.POSITIVE:

1.1 RSV Positive:

The presence of two lines as control line (C) and T1 test line within the result window indicates a positive result for RSV viral antigen.

1.2 COVID-19 Positive:

The presence of two lines as control line (C) and T2 test line within the result window indicates a positive result for COVID-19 viral antigen. If tested COVID-19 positive, users should not take any decision of medical relevance without first consulting a medical practitioner.

1.3 COVID-19+RSV Positive:

The presence of three lines as control line (C), T1 test line and T2 test line within the result window indicates a positive result for RSV and COVID-19 viral antigen.

2.NEGATIVE:

The presence of only control band (C) within the result window indicates a negative result.

3.INVALID:

If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test. If the problem persists, please stop using the product and contact with the test distributor.

NOTE:

- Whether the test result is positive or negative, the used test cassettes, swabs and collection tubes should be put into the collection bag and then disposed of according to local regulations.
- When the test results are positive (regardless of which pathogen tested positive), you are likely infected with Flu A/B, RSV or COVID-19. In case of positive result, you should take

appropriate precautions and seek timely help from a healthcare provider. Individuals who test positive with COVID-19 virus antigen should follow local regulations and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

- When the test result is negative, it means you may not be infected with Flu A/B, RSV or COVID-19. However, there is possibility that a false negative result appears. If you are tested negative but still with symptoms present or you were ever in contact with a suspect, it is necessary to repeat the test after at least 24 hours and no more than 48 hours, or use PCR reagents, or go to the hospital to confirm whether infected with FluA/FluB, RSV or COVID-19.

LIMITATION OF THE TEST

1. This test kit is only used for in vitro diagnosis.
2. This test kit is only used for qualitative detection and cannot indicate the level of antigens in the specimen.
3. This test is not a substitute for a medical consultation and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
4. Failure to follow the instructions for sample collection and testing will lead to erroneous results, and in this case the results are invalid.
5. If the antigen content in the sample is below the detection limit of the product, a false negative result will appear.
6. If the test result is negative, but the symptoms still exist, you need to contact your doctor for confirmation.
7. A negative test result may occur if the specimen is collected, extracted or transported improperly.
8. A negative test result does not rule out the possibility of infection and will not set you free from the local rules to control COVID-19 spread (e.g. contact restrictions and protective measures).
9. A positive test result cannot exclude co-infection with other pathogens.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection (Analytical Sensitivity)

The LoD of Influenza A for Influenza A/B+COVID-19/RSV Combo Ag Test was 1.5×10^4 TCID₅₀/mL, Influenza B for this kit was 1.5×10^6 TCID₅₀/mL, COVID-19 for this kit was 200 TCID₅₀/mL and RSV for this kit was 1.0×10^4 TCID₅₀/mL.

2. High Dose Hook Effect

No high dose hook effect was observed with up to 4.8×10^7 TCID₅₀/mL of Flu A virus, or up to 4.8×10^8 TCID₅₀/mL of Flu B virus, or up to 1.8×10^8 TCID₅₀/mL of SARS-CoV-2, or up to 3.2×10^7 TCID₅₀/mL of RSV with the Influenza A/B+COVID-19/RSV Combo Ag Test.

3. Analytical specificity

For Flu A/B Antigen Test:

3.1 Cross-reactivity

The Flu A/B Antigen Test was evaluated with a total of 36 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 10^7 and 10^9 org/mL. Viral isolates were evaluated at a concentration between 10^4 and 10^8 TCID₅₀/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 TCID₅₀/mL. None of the organisms or viruses listed below gave a positive result in the Flu A/B Antigen Test.

Potential Cross-Reactant	
Virus	Human Adenovirus B
	Human Adenovirus C
	Human Adenovirus 14
	Human Adenovirus type 10
	Human Rhinovirus 16
	Adenovirus type 18
	Measles
	Human Coronavirus OC43
	Mumps
	Human Coxsackievirus A9
Bacteria	Sendai virus
	Coxsackievirus B5
	Parainfluenza virus 2
	Human herpesvirus 2
	Influenza B
	Influenza A
	Human respiratory syncytial virus A
	Parainfluenza virus 3
	Human respiratory syncytial virus B
	SARS-COV-2
	Acinetobacter calcoaceticus
	Bacteroides fragilis
	Neisseria gonorrhoeae
	Neisseria meningitidis
	Pseudomonas aeruginosa
	Staphylococcus aureus
Streptococcus pneumoniae	
Streptococcus sanguis	
Proteus vulgaris	
Streptococcus sp. Gp.B	
Streptococcus sp.Gp.C	
Streptococcus sp. Gp.G	
Mycobacterium tuberculosis	
Mycoplasma orale	
Pooled human nasal wash	

3.2 Interfering Substances

Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the Flu A/B Antigen Test at the levels tested: whole blood (2.5%), three OTC mouthwashes (25%), three OTC nasal sprays (10%), 4-Acetamidophenol (10mg/mL), Acetylsalicylic Acid (20mg/mL), Chlorpheniramine (5mg/mL), Dextromethorphan (10mg/mL), Diphenhydramine (5mg/mL), Ephedrine (20mg/mL), Guaiacol glyceryl ether (20mg/mL), Oxymetazoline (10mg/mL), Phenylephrine (100mg/mL), and Phenylpropanolamine (20mg/mL).

For COVID-19 /RSV Antigen Test:

3.3 Cross-reactivity

Results demonstrated that the COVID-19/RSV Antigen Test has no significant cross-reactivity with the organisms or viruses listed below:

Potential Cross-Reactant	
Virus	Adenovirus
	Human metapneumovirus (hMPV)
	Rhinovirus
	Enterovirus/Coxsackievirus B4
	Human coronavirus OC43
	Human coronavirus 229E
	Human coronavirus NL63
	Human coronavirus HKU1
	Human parainfluenza virus 1
	Human parainfluenza virus 2
Bacteria	Human parainfluenza virus 3
	Human parainfluenza virus 4
	Influenza A H3N2
	Influenza A H1N1
	Influenza A H5N1
	SARS-COV-2
	Respiratory Syncytial Virus A
	Respiratory Syncytial Virus B
	Influenza A H7N9
	Influenza B Guangdong/120/00
Influenza B Yamagata	
MERS-CoV	
Bordetella pertussis	
Chlamydia pneumoniae	
Haemophilus influenzae	
Legionella pneumophila	
Mycoplasma pneumoniae	
Streptococcus pneumoniae	
Streptococcus pyogenes (group A)	
Mycobacterium tuberculosis	
Staphylococcus aureus	
Staphylococcus epidermidis	
Pooled human nasal wash	
Candida albicans	

3.4 Interfering Substances

Whole blood, Mucin, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the COVID-19 /RSV Antigen Test at the levels tested: whole blood (2.5%), Mucin (2%), Phenylephrine (15%), Sodium Chloride (5%), Cromolyn (15%), Oxymetazoline(15%), Fluconazole (5%), Benzocaine (0.15%), Veratramine (20%), Zincum gluconum (i.e., Zicam) (5%), Alkalol (10%), Fluticasone Propionate (5%), Phenol (15%), Tamiflu (Oseltamivir phosphate) (0.5%), Mupirocin (0.25%), Tobramycin (0.0004%).

4. Clinical Performance

Clinical performance characteristics of the CorDx Influenza A/B+COVID-19/RSV Combo Ag Test was evaluated in the clinical studies. A total of 452 symptomatic or asymptomatic subjects were enrolled for the clinical study of the Influenza A/B and RSV test. And a study on 560 symptomatic or asymptomatic suspects of COVID-19 was conducted.

The test results are as follows:

For FLU A antigen detection, the positive coincidence rate is 100.00%, the negative coincidence rate is 99.34%, the total coincidence rate is 99.43%.

For FLU B antigen detection, the positive coincidence rate is 96.00%, the negative coincidence rate is 99.67%, the total coincidence rate is 99.15%.

For RSV antigen detection, the positive coincidence rate is 98.98%, the negative coincidence rate is 99.21%, the total coincidence rate is 99.14%.

For COVID-19 antigen detection, the positive coincidence rate is 89.09%, the negative coincidence rate is 100.00%, the total coincidence rate is 97.86%.

INDEX OF SYMBOLS

	Do not re-use		Batch code
	In vitro diagnostic medical device		Use-by date
	Store at 2-30°C		Consult instructions for use
	Authorized representative in the European Union		Manufacturer
	Do not use if package is damaged and consult instructions for use		Catalogue number
	Keep away from sunlight		Keep dry
	Contains sufficient for <n>tests		CE Mark

MANUFACTURER CONTACT INFORMATION



CorDx, Inc.
9540 Waples St Unit C, San Diego, CA 92121.
Manufacturing site: Core Technology Co., Ltd.
Room 100, C Building, No.29 Life Park Rd.,
Changping District, Beijing 102206, P.R. China

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

Catalogue number:

REF	BP292-01	BP292-02	BP292-04	BP292-05	BP292-25
Model	1 test/box	2 tests/box	1 test/soft pack	5 tests/box	25 tests/box