* Please carefully read the instructions before use
* For in vitro diagnostic and self-testing use

CE 2934

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

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNING AND PRECAUTIONS

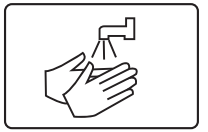
1. Read instructions for use carefully before performing this test.
2. For in vitro diagnostic use only.
3. Do not use the test cassette beyond the expiration date.
4. The test cassette should remain in the sealed pouch until use. Do not use the test cassette if the pouch is damaged or the seal is broken.
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

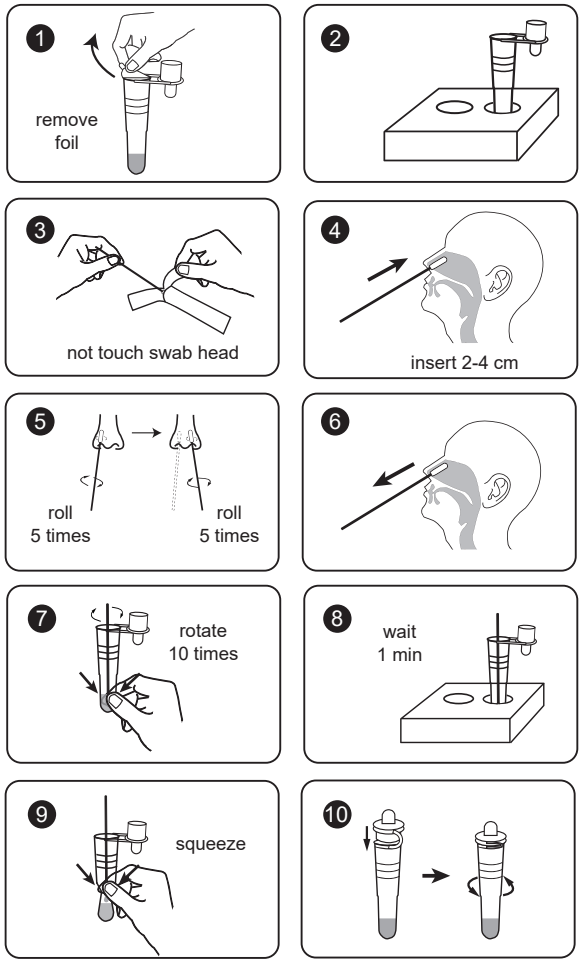
Storage: store at 2~30℃.
Shelf life: 24 months.
The opened cassette should be used within 1 hour.

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.



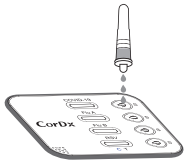
1) Remove the foil from the top of the sample collection tube.
2) Place the tube in the tube rack or the hole on box backside.
3) Remove a sampling swab from the pouch.
4) Using the sterile swab provided in the kit, carefully insert the swab into one nostril.
5) The swab tip should be inserted up to 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



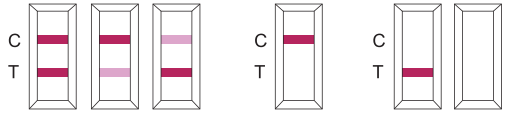
Read the instructions first prior to testing. Bring the pouched test to room temperature prior to testing. Do not open the pouch until ready to begin testing.

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



Positive: Control line and T line appear in the show window.
Negative: Only one line appears in Control area, no line appears in T area.
Invalid: If no line appears in the control area, the test results are invalid regardless of the presence or absence of line in the test area. The direction may not been followed correctly or the test may be deteriorated. It is recommended that repeat the test using a new device. If the problem persist, please stop to use the product and contact local distributor.

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 $TCID_{50}$/mL, Influenza B for this kit was 1.5×10^5 $TCID_{50}$/mL, COVID-19 for this kit was 200 $TCID_{50}$/mL and RSV for this kit was 1.0×10^4 $TCID_{50}$/mL.

2. High Dose Hook Effect

No high dose hook effect was observed with up to 4.8×10^7 $TCID_{50}$/mL of Flu A virus, or up to 4.8×10^8 $TCID_{50}$/mL of Flu B virus, or up to 1.8×10^6 $TCID_{50}$/mL of SARS-CoV-2, or up to 3.2×10^7 $TCID_{50}$/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 Antigen Test and Flu B 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 $TCID_{50}$/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 $TCID_{50}$/mL. None of the organisms or viruses listed below gave a positive result in The Flu A Antigen Test and Flu B Test.

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

COVID-19 AntigenTest and RSV Antigen Test:

3.3 Cross-reactivity

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

Potential Cross-Reactant			
Virus	Adenovirus	Virus	Respiratory Syncytial Virus B
	Human metapneumovirus (hMPV)		Influenza A H7N9
	Rhinovirus		Influenza B Guangdong/120/00
	Enterovirus/Coxsackievirus B4	Bacteria	Influenza B Yamagata
	Human coronavirus OC43		MERS-CoV
	Human coronavirus 229E		Bordetella pertussis
	Human coronavirus NL63		Chlamydia pneumoniae
	Human coronavirus HKU1		Haemophilus influenzae
	Human parainfluenza virus 1		Legionella pnuemophila
	Human parainfluenza virus 2		Mycoplasma pneumoniae
	Human parainfluenza virus 3		Streptococcus pneumoniae
	Human parainfluenza virus 4		Streptococcus pyogenes (group A)
	Influenza A H3N2		Mycobacterium tuberculosis
	Influenza A H1N1		Staphylococcus aureus
	Influenza A H5N1		Staphylococcus epidermidis
	SARS-COV-2		Pooled human nasal wash
	Respiratory Syncytial Virus A		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 gluconium (i.e., Zicam) (5%), Alkalol (10%), Fluticasone Propionate (5%), Phenol (15%), Tamiflu (Oseltamivir hosphate) (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	LOT	Batch code
IVD	In vitro diagnostic medical device		Use-by date
	Store at 2-30˚C		Consult instructions for use
EC REP	Authorized representative in the European Union		Manufacturer
	Do not use if package is damaged and consult instructions for use	REF	Catalogue number
	Keep away from sunlight		Keep dry
n	Contains sufficient for <n>tests	CE	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

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