RightSign®

SARS-CoV-2 + Flu A&B Antigen Combo Rapid Test Cassette（Nasopharyngeal Swab）
Package Insert

REF ICFG-MC83	English

A rapid test for the qualitative detection of SARS-CoV-2, Flu A&B Antigen in Nasopharyngeal swab
For professional in vitro diagnostic use only.

【INTENDED USE】

The SARS-CoV-2 +Flu A&B Antigen Combo Rapid Test Cassette（Nasopharyngeal Swab） is a rapid chromatographic immunoassay for the qualitative detection of *SARS-CoV-2*, Influenza A&B Antigen in Nasopharyngeal swab. It is intended to aid in the rapid differential diagnosis of COVID-19, Influenza A and B infections.

【SUMMARY】

SARS-CoV-2 Antigen Rapid Test Cassette（Nasopharyngeal Swab）

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.

FLU A&B Antigen Rapid Test Cassette（Nasopharyngeal Swab）

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder.

The gold standard of laboratory diagnosis is 14-day cell culture with one of a variety of cell lines that can support the growth of influenza virus. Cell culture has limited clinical utility, as results are obtained too late in the clinical course for effective patient intervention. Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a newer method that is generally more sensitive than culture with improved detection rates over culture of 2-23%. However RT-PCR is expensive, complex and must be performed in specialized laboratories.

【PRINCIPLE】

The SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasopharyngeal swab. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

The FLU A&B Antigen Rapid Test Cassette（Nasopharyngeal Swab） is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in Nasopharyngeal Swab. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as procedural control, a colored line will always appear in the control region if the test has performed properly.

【REAGENTS】

The test cassette contains anti-SARS-CoV-2 Nucleocapsid protein particles ,anti-Influenza A &B particles and anti- SARS-CoV-2 Nucleocapsid protein, anti-Influenza A & B coated on the membrane.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
4. The used test should be discarded according to the local regulations.
5. Avoid using bloody samples.
6. Wear gloves when handling the samples, avoid touching the reagent membrane and sample well.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30℃). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

● Nasopharyngeal swab

Insert swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

【MATERIALS】

Materials provided

Test cassettes	Extraction Reagent	Extraction Tubes	Dropper tips
Sterile Swabs	Package Insert	Workstation	

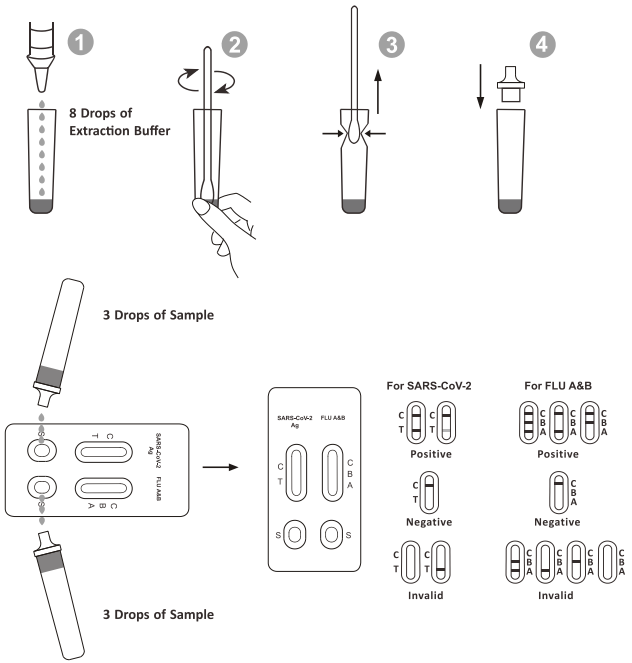
Materials required but not provided

Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 8 drops of solution (Approx. 300μL) to the Extraction Tube. See illustration 1.
3. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.
4. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4
6. Add 3 drops of the solution (approx.80μL) to the sample well and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* A colored line appears in the Control region (C) and colored line(s) appears in the Test region (T, A and/or B). A positive result in the SARS-CoV-2 region indicates that SARS-CoV-2 was detected in the specimen, a positive result in the Influenza A region indicates that Influenza A antigen was detected in the specimen, a positive result in the Influenza B region indicates that Influenza B antigen was detected in the specimen.

***NOTE:** The shade of the colored lines(s) in the Test region (T, A and/or B) may vary. The result should be considered positive whenever there is even a faint line.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T, A and B). A negative result indicates that SARS-CoV-2, Influenza A&B antigen are not present in the specimen, or is present below the detectable level of the test.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The SARS-CoV-2+Flu A&B Antigen Combo Rapid Test Cassette（Nasopharyngeal Swab）is for professional in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2, Influenza A&B Antigen in Nasopharyngeal swab. Neither the quantitative value nor the rate of increase in SARS-CoV-2 virus, Influenza A&B virus concentration can be determined by this qualitative test.
2. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
3. The SARS-CoV-2+Flu A&B Antigen Combo Rapid Test Cassette（Nasopharyngeal Swab）will only indicate the presence of SARS-CoV-2, Influenza A&B in the specimen from both viable and non-viable SARS-CoV-2 coronavirus, Influenza A and B strains.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. A negative result obtained from this kit should be confirmed by PCR. A negative result may be obtained if the concentration of the SARS-CoV-2, Influenza A&B virus present in the swab is not adequate or is below the detectable level of the test.
6. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
7. Positive result for SARS-CoV-2, Influenza A and/or B do not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
8. Negative results do not rule out SARS-CoV-2, Influenza A and/or B infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
10. SARS-CoV-2 positive results may be due to present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
11. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2, Influenza A &B infection or to inform infection status.

【PERFORMANCE CHARACTERISTICS】

Sensitivity, Specificity and Accuracy

The SARS-CoV-2+Flu A&B Antigen Combo Rapid Test Cassette（Nasopharyngeal Swab）has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the SARS-CoV-2+Flu A&B Antigen Combo Rapid Test Cassette（Nasopharyngeal Swab）. Specimens were considered positive if PCR indicated a positive result.

SARS-CoV-2 + Flu A&B Antigen Combo Rapid Test Cassette	Type A			Type B			SARS-CoV-2		
	RT-PCR		Total	RT-PCR		Total	RT-PCR		Total
	Positive	Negative		Positive	Negative		Positive	Negative	
Positive	68	14	82	49	7	56	38	3	41
Negative	10	242	252	4	274	283	2	360	362
Total	78	256	334	53	281	334	40	363	403
Relative Sensitivity	87.2%			92.5%			95.0%		
Relative Specificity	94.5%			97.5%			99.2%		

Accuracy	92.8%	96.7%	98.8%

Detection Limit of SARS-CoV-2

The LOD for the SARS-CoV-2 Antigen Rapid Test Cassette(Nasopharyngeal Swab) was established using limiting dilutions of a viral sample inactivated. The material(ZeptoMetrix, 0810587CFHI) was supplied at a concentration of 1.15 x 10^7TCID$_{50}$/mL. The Estimated LOD is 1000 TCID $_{50}$/mL.

Reactivity with Human Influenza Strain

Influenza A strains

Subtype of H1N1: Mal/302/54, New Jersey/8/76, NWS/33, WS/33, Guangdong-Maonan/SWL1536/2019; H3N2: Aichi/2/68, Hong Kong/8/68, Port Chalmers/1/73, Hong Kong/2671/2019; H7N9 Anhui/1/2013, all are positive.

Influenza B strains

Russia/69, Hong Kong/5/72, Lee/40, Brigit, R5, Wisconsin/1/2010, Florida/78/2015, Phuket/3073/2013, Washington/02/2019, all are positive.

Cross Reactivity

The SARS-CoV-2 Antigen Rapid Test Cassette (Nasopharyngeal Swab) has been tested for Influenza A virus, Influenza B virus, Adenovirus, Coxsackie virus, Parainfluenza Virus Type1, Parainfluenza Virus Type2, Parainfluenza Virus Type3, Parainfluenza Virus Type4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, Bordetella pertussis, Haemophilus parainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, Streptococcus sp. group B, Streptococcus sp. group C, Candida albicans, Human Metapneumovirus (hMPV),Bordetella pertussis, Legionella pneumophila, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Pneumocystis jirovecii(PJP)-S cerevisiae Recombinant, Pseudomonas aeruginosa, Staphylococcus epidermis, Streptococcus pneumoniae, Streptococcus salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus positive specimens.The results showed no cross reactivity.

The **FLU A&B Antigen Rapid Test Cassette（Nasopharyngeal Swab）** has been tested for Adenovirus, Coxsackie virus, Cytomegalovirus, Parainfluenza Virus Type1,2,3,4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, Bordetella pertussis, Haemophilusparainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, B, C. The results showed no cross reactivity.

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Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #
	Do not use if package is damaged				

EC REP
CMC Medical Devices & Drugs S.L.
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