SARS-Cov-2＆Influenza A＆B Combo Rapid Test Cassette (swab) Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS, INFLUENZA A&B VIRUS IN NASOPHARYNGEAL SWAB.
For professional In Vitro Diagnostic Use Only.

INTENDED USE

SARS-Cov-2＆Influenza A＆B Combo Rapid Test Cassette (swab) is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens and influenza A and B antigens in Nasopharyngeal swab,using the rapid immunochromatographic method. It will provide information for clinical doctors to prescribe correct medications.

SUMMARY

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.

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.The Influenza A&B Rapid Test device qualitatively detects the presence of Influenza A and/or Influenza B antigen in nasal swab or throat swab or nasal aspirate specimens,providing results within 15 minutes.The test uses antibodies specific for Influenza A and Influenza B to selectively detect Influenza A and Influenza B antigen in nasal swab,throat swab or nasal aspirate specimens.

PRINCIPLE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coroinavirus.The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus;the reaction membrane contains the secondary antibodies for Novel coroinavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.When the sample is added into the sample window,conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coroinavirus is present in the sample, a complex formed between the anti- Novel coroinavirus conjugate and the virus will be caught by the specific anti-Novel coroinavirus monoclonal coated on the T region. Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

The Influenza A&B Rapid Test is a qualitative,lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasal swab,throat swab or nasal aspirate specimens. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test device.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 a procedural control, a colored line will always appear in the control region if the test has performed properly.

REAGENTS

The reagent membrane for SARS-Cov-2 test contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus, the reaction membrane contains the secondary antibodies for Novel coroinavirus,and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane; the reagent membrane for Influenza A&B test contains anti-Influenza A and B particles and anti- Influenza A and B coated on the membrane.

PRECAUTIONS

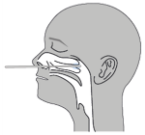
- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform test at room temperature 15 to 30°C.
- Wear gloves when hanging the samples, avoid touching the reagent membrane and sample window.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.
- Avoid using bloody samples.

STORAGE AND STABILITY

Store the Rapid Test Cassette at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

SPECIMEN COLLECTION AND PREPARATION

1. Specimen collection:



It is applicable to the diagnosis of the Novel coroinavirus or Influenza A&B virus from the samples of Nasopharyngeal swab.Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result. Completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.

It is recommended to collect sample from Nasopharyngeal for more accurate results.

2. Specimen preparation:

1) Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube.

2) **Nasopharyngeal Swabbing**

Insert the swab into the extraction tube which contains Sample Extraction Buffer. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that liquid is expressed and reabsorbed from the swab, remove the swab. The extracted solution will be used as test sample.

MATERIALS

Materials provided

- Test Device
- Sterilized Swab
- Extraction Tube
- Package Insert
- Nozzle
- Sample Extraction Buffer
- Tube Stand*

*The 25-test package contains the tube stand，the 5-test package use the test box itself as tube stand.

Materials required but not provided

- Timer

DIRECTIONS FOR USE

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

1.Remove the test device from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

2. Take out the Extraction Tube.

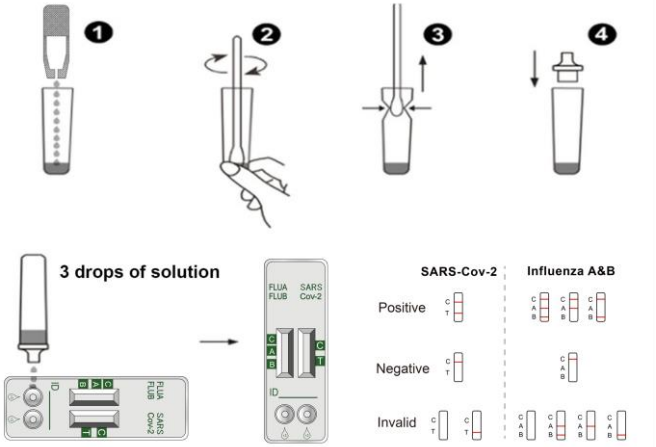
3. Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube.

4.Place the sterilized swab specimen in the sample extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

5.Remove the sterilized swab while squeezing the sterilized swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the sterilized swab in accordance with your biohazard waste disposal protocol.

6. Screw on and tighten the Nozzle with Filter onto the specimen collection tube, then **shake the specimen collection tube vigorously** to mix the specimen and the sample extraction buffer. See illustration 4.

7.Add 3 drops of the solution (approx.80ul) to each sample well and then start the timer. Read the result at 10~20 minutes. Don't interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE SARS-Cov-2: Two red lines appear. One red line appears in the control region(C), and one red line in the test region(T).

POSITIVE Influenza A: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B: Three distinct colored lines appear. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B).A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

*NOTE: The shade of color may vary，but it should be considered positive whenever there is even a faint line.

NEGATIVE: Only one red line appears in the control region(C), and no line in the test region(T/A/B).

INVALID: No red line appears in the control region(C). The test is invalid even if there is a line on test region(T/A/B). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- The Test is for professional in vitro diagnostic use only. The test should be used for the detection of Influenza A and/or B virus and/or novel coronavirus antigens in Nasopharyngeal swab. Neither the quantitative value nor the rate of increase in Influenza A and/or B virus and/or novel coronavirus antigens concentration can be determined by this qualitative test.
- The Test is an acute-phase screening test for qualitative detection. Sample collected may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection.
- The Test detects viable and non-viable Influenza A and/or B virus and/or novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present, therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
- Positive test results do not rule out co-infections with other pathogens.
- The negative test results for novel coronavirus are not intended to rule in other coronavirus infection except the SARS-Cov-2.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children List.
- A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility infection, and should be confirmed by viral culture or PCR.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
- 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.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

1.SARS-Cov-2

Clinical evaluation was performed to compare the results obtained by The SARS-Cov-2 Antigen Rapid Test and PCR. The results were summarized below:

Table: SARS-Cov-2 Antigen Rapid Test vs. PCR

Method		2019-nCoV Nucleic Acid Test Kit (RT-PCR)		Total Results
The SARS-Cov-2 Antigen Rapid Test	Results	Positive	Negative	
	Positive	201	0	201
	Negative	8	450	458
Total Results		209	450	659

Clinical sensitivity = 201/209=96.17 % (95%CI* 92.51% to 98.17%)
Clinical specificity = 450/450＞99.9% (95%CI* 98.98% to 100%)
Accuracy: (201+450)/ (201+0+8+450) *100%=98.79% (95%CI* 97.58% to 99.43%)
*Confidence Interval

2. Influenza A&B

Clinical evaluation was performed to compare the results obtained by The Influenza A&B Rapid Test and PCR. The results were summarized below:

Table: Influenza A&B Rapid Test vs. PCR

		Type A			Type B		
		RT-PCR		Total Results	RT-PCR		Total Results
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	58	1	59	65	1	66
	Negative	3	150	153	4	162	166
Total Results		61	151	212	69	163	232
Relative Sensitivity		95.1%			94.2%		
Relative Specificity		99.3%			99.4%		

Accuracy	98.1%	97.8%

Cross Reaction

1.SARS-Cov-2

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Virus/Bacteria/Parasite	Strain	Concentration
MERS-coronavirus	N/A	72 μg/mL
Adenovirus	Type 1	1.5 x 10^6TCID$_{50}$/mL
	Type 3	7.5 x 10^6TCID$_{50}$/mL
	Type 5	4.5 x 10^6TCID$_{50}$/mL
	Type 7	1.0 x 10^6TCID$_{50}$/mL
	Type 8	1.0 x 10^6TCID$_{50}$/mL
	Type 11	2.5 x 10^6TCID$_{50}$/mL
	Type 18	2.5 x 10^6TCID$_{50}$/mL
	Type 23	6.0 x 10^6TCID$_{50}$/mL
	Type 55	1.5 x 10^6TCID$_{50}$/mL
Influenza A	H1N1 Denver	3.0 x 10^8TCID$_{50}$/mL
	H1N1 WS/33	2.0 x 10^8TCID$_{50}$/mL
	H1N1 A/Mal/302/54	1.5 x 10^8TCID$_{50}$/mL
	H1N1 New Caledonia	7.6 x 10^8TCID$_{50}$/mL
	H3N2 A/Hong Kong/8/68	4.6 x 10^8TCID$_{50}$/mL
Influenza B	Nevada/03/2011	1.5 x 10^8TCID$_{50}$/mL
	B/Lee/40	8.5 x 10^8TCID$_{50}$/mL
	B/Taiwan/2/62	4.0 x 10^8TCID$_{50}$/mL
Respiratory syncytial virus	N/A	2.5 x 10^6TCID$_{50}$/mL
Legionella pneumophila	Bloomington-2	1 x 10^5 PFU/mL
	Los Angeles-1	1 x 10^5 PFU/mL
	82A3105	1 x 10^5 PFU/mL
Rhinovirus A16	N/A	1.5 x 10^6TCID$_{50}$/mL
Mycobacterium tuberculosis	K	1 x 10^5PFU/mL
	Erdman	1 x 10^5PFU/mL
	HN878	1 x 10^5PFU/mL
	CDC1551	1 x 10^5PFU/mL
	H37Rv	1 x 10^5PFU/mL
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	1 x 10^5PFU/mL
	178 [Poland 23F-16]	1 x 10^5PFU/mL
	262 [CIP 104340]	1 x 10^5PFU/mL
	Slovakia 14-10 [29055]	1 x 10^5PFU/mL
Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF 130]	1 x 10^5PFU/ml
Mycoplasma pneumoniae	Mutant 22	1 x 10^5PFU/ml
	FH strain of Eaton Agent [NCTC 10119]	1 x 10^5PFU/ml
	36M129-B7	1 x 10^5PFU/ml
Coronavirus	229E	1.5 x10^6TCID$_{50}$/ml
	OC43	1.5 x10^6TCID$_{50}$/ml
	NL63	1.5 x 10^6TCID$_{50}$/ml
	HKU1	1.5 x 10^6TCID$_{50}$/ml
Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002	1.5 x 10^6TCID$_{50}$/ml
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	1.5 x 10^6TCID$_{50}$/ml
Parainfluenza virus	Type 1	1.5 x 106TCID$_{50}$/ml
	Type 2	1.5 x 106TCID$_{50}$/ml
	Type 3	1.5 x 106TCID$_{50}$/ml
	Type 4A	1.5 x 106TCID$_{50}$/ml

2. Influenza A&B

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Description	Concentration
Human adenovirus C	5.62 x 10^5 TCID$_{50}$/ml
Human adenovirus B	1.58 x 10^4 TCID$_{50}$/ml
Adenovirus type 10	3.16 x 10^3 TCID$_{50}$/ml
Adenovirus type 18	1.58 x 10^4 TCID$_{50}$/ml
Human coronavirus OC43	2.45 x 10^6 LD$_{50}$/ml
Coxsackievirus A9	2.65 x 10^4 LD$_{50}$/ml
	1.58 x 10^5 TCID$_{50}$/ml
Coxsackievirus B5	1.58 x 10^7 TCID$_{50}$/ml
Human herpesvirus 5	1.58 x 10^4 TCID$_{50}$/ml
Echovirus 2	3.16 x 10^5 TCID$_{50}$/ml
Echovirus 3	1 x 104 TCID$_{50}$/ml
Echovirus 6	3.16 x 10^6 TCID$_{50}$/ml
Herpes simplex virus 1	1.58 x 10^6 TCID$_{50}$/ml
Human herpesvirus 2	2.81 x 10^5 TCID$_{50}$/ml
Human Rhinovirus 2	2.81 x 10^4 TCID$_{50}$/ml
Human Rhinovirus 14	1.58 x 10^6 TCID$_{50}$/ml
Human Rhinovirus 16	8.89 x 10^6 TCID$_{50}$/ml
Measles	1.58 x 10^4 TCID$_{50}$/ml
Mumps	1.58 x 10^4 TCID$_{50}$/ml
Sendai virus	8.89 x 10^7 TCID$_{50}$/ml
Parainfluenza virus 2	1.58 x 10^7 TCID$_{50}$/ml
Parainfluenza virus 3	1.58 x 10^8 TCID$_{50}$/ml
Respiratory syncytial virus	8.89 x 10^4 TCID$_{50}$/ml
Human respiratory syncytial virus	1.58 x 10^5 TCID$_{50}$/ml
Rubella	2.81 x 10^5 TCID$_{50}$/ml
Varicella-Zoster	1.58 x 10^3 TCID$_{50}$/ml
Arcanobacterium	1.0x10^8 org/ml
Candida albicans	1.0x10^8 org/ml
Corynebacterium	1.0x10^8 org/ml
Enterococcus faecalis	1.0x10^8 org/ml
Enterococcus faecium	1.0x10^8 org/ml
Escherichia coli	1.0x10^8 org/ml
Haemophilus	1.0x10^8 org/ml
Moraxella catarrhalis	1.0x10^8 org/ml
Neisseria gonorrhoeae	1.0x10^8 org/ml
Neisseria lactamica	1.0x10^8 org/ml
Pseudomonas aeruginosa	1.0x10^8 org/ml
Staphylococcus aureus subspaureus	1.0x10^8 org/ml
Staphylococcus epidermidis	1.0x10^8 org/ml
Staphylococcus saprophylicus	1.0x10^8 org/ml
Streptococcus agalactiae	1.0x10^8 org/ml
Streptococcus bovis	1.0x10^8 org/ml
Streptococcus dysgalatiae / subsp.dysgalatiae	1.0x10^8 org/ml
Streptococcus oralis formerly Streptococcus	1.0x10^8 org/ml
Streptococcus pneumoniae	1.0x10^8 org/ml
Streptococcus pygenes	1.0x10^8 org/ml

Interfering Substances Reaction

When tested using the SARS-Cov-2＆Influenza A＆B Combo Rapid Test Cassette (swab), there was no interference between the device reagents and the Potential interference substances listed in below table that would create false positive or negative results.

Substance	Concentration	Substance	Concentration
Mucin	100μg/mL	Acetylsalicylic acid	3.0 mM
Whole Blood	5% (v/v)	Ibuprofen	2.5 mM
Biotin	100μg/mL	Mupirocin	10 mg/mL
Neo-Synephrine (Phenylephrine)	5%(v/v)	Tobramycin	10μg/mL
Afrin Nasal Spray (Oxymetazoline)	5%(v/v)	Erythromycin	50uM
Saline Nasal Spray	5%(v/v)	Ciprofloxacin	50uM
Homeopathic	5%(v/v)	Ceftriaxone	110mg/mL
Sodium Cromoglycate	10 mg/mL	Meropenem	3.7μg/mL
Olopatadine Hydrochloride	10 mg/mL	Tobramycin	100μg/mL
Zanamivir	5 mg/mL	Histamine Hydrochloride	100μg/mL
Oseltamivir	10 mg/mL	Peramivir	1mmol/mL
Artemether-lumefantrine	50uM	Flunisolide	100μg/mL
Doxycycline hyclate	50uM	Budesonide	0.64nmol/ L
Quinine	150uM	Fluticasone	0.3ng/mL
Lamivudine	1 mg/mL	Lopinavir	6μg/mL
Ribavirin	1 mg/mL	Ritonavir	8.2mg/mL
Daclatasvir	1 mg/mL	Abidor	417.8ng/mL
Acetaminophen	150uM	Pooled human nasal wash	N/A

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

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CE

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