SARS-CoV-2, Influenza Virus and Respiratory Syncytial Virus Multiple Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

Product Identification

Product Name: SARS-CoV-2, Influenza Virus and Respiratory Syncytial Virus Multiple Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

Reference Number: S3148E-24, S3148E-48, S3148E-24-P, S3148E-12-S

Package Specification: 24 tests/kit, 48 tests/kit, Pre-packaged 24 tests/kit, Pre-packaged 12 tests/kit

Intended Use

The SARS-CoV-2, Influenza Virus and Respiratory Syncytial Virus Multiple Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is a real-time RT-PCR (RT-qPCR) test intended for the qualitative Diagnostic of nucleic acid from SARS-CoV-2, Influenza Virus A/B (Flu) and Respiratory Syncytial Virus (RSV) Multiple in the nasopharyngeal swabs and oropharyngeal swabs from individuals. Results are for the identification of SARS-CoV-2, Flu and RSV Multiple RNA, and should not be used as the sole basis for patient management decisions.

As the seventh coronavirus that infects humans, the SARS-CoV-2 can cause fever, fatigue, dry cough, dyspnea and other symptoms. In severe cases, it can cause acute respiratory distress syndrome, septic shock, and even death[1]. At the same time, the SARS-CoV-2 has a strong spreading ability and has a wide range[2]. Since the outbreak of the SARS-CoV-2, it has rapidly spread to many provinces and cities across the country and many countries in the world and become a threat to human life and health[3]. Flu can cause acute respiratory infections, with clinical manifestations of fever, headache, myalgia, fatigue, rhinitis, sore throat and cough[4]. Flu can aggravate underlying diseases (such as heart and lung diseases) or cause secondary bacterial pneumonia or primary influenza viral pneumonia[5]. The elderly and people with various chronic diseases or physical weakness are prone to severe complications and mortality higher after infecting influenza[6]. RSV belongs to the Pneumovirus genus of the Paramyxoviridae family. It mainly causes lower respiratory tract infections such as bronchiolitis and pneumonia in infants under 6 months, as well as rhinitis, cold and other upper respiratory tract infections in older children and adults[7].

The kit is intended for use by professional, qualified, trained clinical laboratory personnel specifically instructed and trained in the techniques of RT-qPCR and *in vitro* diagnostic procedures.

For in vitro diagnostic use only. For professional use only.

Test principle summary and explanation

Summary

The SARS-CoV-2, Flu and RSV RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, Flu and RSV RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2, Flu and RSV infection. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Test Principle

The kit is a RT-qPCR test. The SARS-CoV-2, Flu and RSV primer and probe sets are designed to detect RNA from SARS-CoV-2, Flu and RSV in respiratory and other specimens from patients who are suspected of SARS-CoV-2, Flu and RSV infection. This kit is used for qualitative detection of the ORF1ab and N genes of SARS-CoV-2, the M gene of FluA, the NP gene of FluB, and the M gene of RSV.

An internal control targeting the RNase P gene monitors the sample collection, sample handling and RT-qPCR process to avoid false-negative results.

Materials provided

This kit is an amplification reaction reagent and contains the following components:

No.	Reagent Name	Spec. & Qty.				Main Ingredients
		24 T	48 T	Pre-packaged 24T	Pre-packaged 12T	
1	SARS-CoV-2-Flu-RSV-PCR Mix	624 μL/tube x 1 tube	1248 μL/tube x 1 tube	26 μL/tube x 24 tubes	26 μL/tube x 12 tubes	Primers, Probes, RNasin, dNTPs, $MgCl_2$, PCR buffer
2	SARS-CoV-2-Flu-RSV-Enzyme Mix	96 μL/tube x 1 tube	192 μL/tube x 1 tube	4 μL/tube x 24 tubes	4 μL/tube x 12 tubes	Reverse Transcriptase, Taq DNA Polymerase
3	SARS-CoV-2-Flu-RSV-Positive Control	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	Pseudovirus particles containing target genes and internal control gene fragments (RNase P)
4	SARS-CoV-2-Flu-RSV-Negative Control	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	1000 μL/tube x 1 tube	Normal Saline

Materials required but not provided

1. Materials required but not provided: 1.5 mL DNase-free and RNase-free microfuge tubes; 0.2 mL PCR reaction tubes or strip; Various models of pipettes and pipette tips (10 μL, 200 μL and 1000 μL tips with filters); Microcentrifuge; Vortex mixer.
2. Reagent required but not provided: Nucleic Acid Extraction-Purification Kit (Reference Number: S50016E Series) manufactured by Sansure Biotech Inc. and Sample Release Reagent (Reference Number: S1014E Series) manufactured by Sansure Biotech Inc.

Warnings and precautions

Warnings

1. Do not mix or exchange components from different kits.
2. All biological materials in the kit have been inactivated.

Precautions

1. For *in vitro* diagnostic use only. Please read the product manual carefully before operation.
2. Please learn and be familiar with the operation procedures and precautions for each instrument before test. Please make sure quality control is performed for each test.
3. Laboratory management shall strictly follow management practices of PCR gene amplification laboratory, laboratories personnel must receive professional training, test processes must be performed in separated regions, all consumables should be for single use only after sterilization, special instruments and devices should be used for every process, all lab devices required in different processes and regions should not be cross-used.
4. All samples for detection should be handled as potentially infectious. Wear laboratory coats, protective disposable gloves and change the gloves often to avoid cross-contamination between samples. Handling of samples and waste must meet relevant requirements outlined in local, state and national regulations.
5. Note: Improper operation during the storage, transportation and use of the reagent may affect the test results. For example, improper storage and transportation, sample collection, sample processing and test process are not standardized. Please strictly follow the instructions.
6. Due to the characteristics of swab and other sample collection process and viral infection process itself, false negative results may be caused by insufficient sample volume, which should be combined with other clinical diagnosis and treatment information for comprehensive judgment, retest when necessary.
7. After the addition of the sample in the tube the resulting solution is to be considered potentially biohazardous, handle the reagent with appropriate precautions and good laboratory practice.
8. The safe disposal of the reagents supplied must be carried out according to the instruction contained in the specific Safety Data Sheets and in compliance with the national regulations on disposal of potentially hazardous waste.
9. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established; If you have any questions about the test or the results, please contact Sansure`s customer service hotline +86-731-88883176-6116 or send an email to info@sansure.com.cn/support@sansure.com.cn.

IVD storage, operating conditions and stability

1. The shelf life of the kit is 12 months at -25°C to -15°C and protected from light.
2. Please refer to the date of manufacture and expiry date printed on the outside of the box.
3. Unopened reagents are valid and stable until the expiry date.
4. Once the reagents are opened, the maximum number of freeze/thaw cycles should not exceed three.
5. The reagents keep valid and stable before the expiry date on the outer package when transporting for 7 days in a sealed foam box containing coolant with the temperature lower than 20℃.

Instrumentation

The diagnostic kit is compatible to Fluorescence Quantitative Analysis System containing FAM, HEX, ROX and CY5 channels such as:

1. Angilent/AriaDx Real-Time PCR System
2. Applied Biosystems/7500 Real-Time PCR System
3. Bio-Rad/CFX96 Dx and CFX96 Deepwell Dx Systems
4. Hongshi/SLAN®-96P Real-Time PCR System
5. Molarray/Real-Time Quantitative Thermal Cycler (Model: MA-6000)
6. Roche/LightCycler® 480 instrument II
7. Sansure/Portable Molecular Diagnostic System (S-Q37A/S-Q37B)
8. Sansure/Portable Molecular Workstation (Model: S-Q36A)
9. Sansure/Portable Molecule Workstation (Model: S-Q31A/S-Q31B)
10. Thermofisher/QuantStudio™ 5 Real-Time PCR System

Collecting and preparing specimens

1. Applicable specimen type: nasopharyngeal swab and oropharyngeal swab.
2. Collection of specimen

Nasopharyngeal swab/oropharyngeal swab: Collect samples in accordance with the relevant local procedures for COVID-19 Laboratory Testing. Collection swabs should have a synthetic tip, such as nylon or Dacron®, and an aluminium or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended.

Nasopharyngeal swab: The specimen collection tube should be pasted with the barcode first; the nasopharyngeal swab should be collected within 3 days after the onset of the disease as far as possible. Use swab to measure the length between apex nasi and earlobe, then mark with finger. Insert the swab into the nasal cavity in direction of perpendicular to the nose (face). The swab should be inserted at least half of the length from the earlobe to the apex nasi. Make the swab stops in the nasal for 15 to 30 seconds, gently rotate 3 to 5 times, quickly put swab into specimen collection tube containing 2 mL Lysis Buffer (same as Lysis Buffer in the Sample Release Reagent) or Sample Storage Reagent containing RNA enzyme inhibitor. Insert the swab, then break the sterile swab rod near the top, tighten tube cap and seal with sealing film.

Oropharyngeal swab: The specimen collection tube should be pasted with the barcode first; the oropharyngeal swab should be collected within 3 days after the onset of the disease as far as possible. A sterile flocking swab should be used for sampling, moderately wipe the posterior pharyngeal wall, avoid touching the tongue. Quickly place a sterile swab into the collection tube used for collection of oropharyngeal swabs. Break the sterile swab rod near the top, tighten tube cap and seal with sealing film

3. Storage and delivery of specimens:

Specimens to be tested can be immediately processed, specimens to be tested within 24 hours can be stored at 4℃. Specimens that cannot be detected within 24 hours should be stored at -70℃ or below (in the absence of -70℃ storage conditions, specimens to be tested can be stored at -25℃ to -15℃ for 10 days, nucleic acid can be stored at -25℃ to -15℃ for 15 days). Multiple freeze/thaw cycles should be avoided. Specimens should be transported in a sealed frozen container with ice or in a sealed foam box with ice packs.

Test procedure

1. Please process according to the following steps for AriaDx Real-Time PCR System, SLAN®-96P Real-Time PCR System, 7500 Real-Time PCR System, QuantStudio™ 5 Real-Time PCR System, LightCycler® 480 instrument II,Real-Time Quantitative Thermal Cycler (Model: MA-6000), CFX96 Dx and CFX96 Deepwell Dx Systems instrument:

1.1 Preparation of reagent (performed at "reagent preparation region")

1.1.1 Take out all the components out off the diagnostic kit and equilibrate them at room temperature, then vortex each of them respectively for later use.

1.1.2 Prepare the SARS-CoV-2-Flu-RSV-PCR Master Mix according to following table. The volume required is based on the total number of specimens, plus a SARS-CoV-2-Flu-RSV-Positive Control and a SARS-CoV-2-Flu-RSV-Negative Control. Mix thoroughly then centrifuge it for later use. The remaining reagent must be stored at -20℃ immediately.

	1 sample	10 samples	24 samples	48 samples
SARS-CoV-2-Flu-RSV-PCR Mix (μL)	26	260	624	1248
SARS-CoV-2-Flu-RSV-Enzyme Mix (μL)	4	40	96	192

Note: The above configuration is for reference only.

1.2. Processing and loading of specimens (performed at "specimen processing region")

1.2.1 Use Nucleic Acid Extraction-Purification Kit (Reference Number: S50016E Series) manufactured by Sansure Biotech Inc. to do sample extraction. Take 300μL sample, or SARS-CoV-2-Flu-RSV-Negative Control, or SARS-CoV-2-Flu-RSV-Positive Control to extract the nucleic acid according to corresponding manual.

Or use Sample Release Reagent (Reference Number : S1014E Series) manufactured by Sansure Biotech Inc. to extract the nucleic acid according to corresponding manual. Add 10 μL sample, or SARS-CoV-2-Flu-RSV-Negative Control, or SARS-CoV-2-Flu-RSV-Positive Control to 10 μL Sample Release Reagent (Reference Number : S1014E Series), mix well and leave at room temperature for 10 minutes.

1.2.2 Add 20 μL of the extracted RNA to the PCR tubes in the following order: SARS-CoV-2-Flu-RSV-Negative Control, patient specimen(s), and SARS-CoV-2-Flu-RSV-Positive Control.

1.2.3 Add 30 μL of SARS-CoV-2-Flu-RSV-PCR Master Mix into each well. Cover each well, centrifuge at 2000 rpm for 10 seconds, and place into the Real-Time PCR system.

1.3 PCR Amplification (Refer to user manual of each instrument to adjust the settings.)

1.3.1 Place PCR reaction tubes into the specimen wells of the amplification equipment. Set up the SARS-CoV-2-Flu-RSV-Positive Control, SARS-CoV-2-Flu-RSV-Negative Control and specimens to be tested in order and input specimen name.

1.3.2 Select PCR test channel:

a) Select FAM channel to test SARS-CoV-2 nucleic acid.

b) Select HEX/VIC channel to test Flu nucleic acid.

c) Select ROX channel to test RSV nucleic acid.

d) Select CY5 channel to test internal control.

1.3.3 Set cycle parameters

	Steps	Temperature	Time	Cycle No.
1	Reverse transcription	50℃	10 min.	1
2	cDNA pre-denaturation	94℃	1 min.	1
3	Denaturation	94℃	10 sec.	45
	Annealing, extension and fluorescence collection	60℃	20 sec*.	

***Note:** This cannot be set to 20 seconds due to ABI 7500 instruments, but can be set to 31 seconds.

When the settings are completed, save the settings and carry out the reaction procedure.

2. Please process according to the following steps for Portable Molecule Workstation (Model: S-Q31A&B):

2.1 Preparation of consumables and reagents

2.1.1 Take out the reaction tube carrier, PCR reaction tube and Tip;

2.1.2 Put the Tip into **Well** H, and PCR reaction tube into **Well** PCR (The well location information has been marked on the reaction tube carrier);

2.1.3 Put Sample Release Reagent (Reference Number : S1014E Series) into the **Well** B; Put SARS-CoV-2-Flu-RSV-PCR Mix into the **Well** C; Put SARS-CoV-2-Flu-RSV-Enzyme Mix into the **Well** D;

2.1.4 Add 20μL sample to be tested or SARS-CoV-2-Flu-RSV-Positive Control or SARS-CoV-2-Flu-RSV-Negative Control into the **Well** B (To avoid bubbles during operation, it is recommended to pipet deeply and release slowly).

2.2 Test Procedure (Refer to user manual of each instrument to adjust the settings.)

2.2.1 Press the front door to open it.

2.2.2 Place the **Well A** of reagent strip into the instrument towards the outside of the instrument, and close the front door of the instrument.

2.2.3 Click the**"Lab task"** on the instrument display screen to enter the interface of setting new lab task.

2.2.4 Select the required Lab project in the drop-down menu of **Lab project**, enter the corresponding task name in the **Task Name** bar, and input and select other items that should be input or selected.

2.2.5 Click **"Submit"** to submit the lab task and **"OK"** to run the instrument and start the lab task successively.

2.2.6 When the Portable Molecule Workstation (Model: S-Q31B) shows **"Please transfer the PCR tube to the 1/2/3/4"** (The S-Q31A shows "Please transfer the PCR tube") on the interface, take out the PCR tube and cover it well, then centrifuge it instantaneously.

2.2.7 Insert the PCR tube into the PCR amplification module (the "PCR 1/2/3/4" cover has been automatically opened at this time), close the PCR lid of the amplification module, then click **"OK"** for amplification detection.

3. Please process according to the following steps for Portable Molecular Workstation (Model: S-Q36A):

3.1 Preparation of consumables and reagents

3.1.1 Take out the Consumables kits and reagents.
3.1.2 Put Sample Release Reagent (Reference Number: S1014E Series) into the **Well** B; Put SARS-CoV-2-Flu-RSV-PCR Mix into the **Well** C; Put SARS-CoV-2-Flu-RSV-Enzyme Mix into the **Well D**, (The well location information has been marked on the carrier set).
3.1.3 Add 20μL sample to be tested or SARS-CoV-2-Flu-RSV-Positive Control or SARS-CoV-2-Flu-RSV-Negative Control into the **Well** B (To avoid bubbles during operation, it is recommended to pipet deeply and release slowly).

3.2 Test Procedure

3.2.1 Click the "" and "" button on the instrument display screen to open the door of the instrument and put the prepared consumables into the designated position of the instrument.
3.2.2 Click the "New" on the instrument display screen to enter the new experiment task setting interface.
3.2.3 Select the Lab project project in the drop-down menu of **Lab project**, enter the corresponding task name in the Task Name bar, and input and select other items that should be input or selected.
3.2.4 Click "Submit" to submit the lab task and "OK" to run the instrument and start the lab task successively.

4. Please process according to the following steps for Portable Molecular Diagnostic System (S-Q37A/S-Q37B):

4.1 Pre-run preparation

4.1.1 Load the amplification reagent component assembly into the extraction reagent component (Nucleic Acid Extraction-Purification Kit, Reference Number: S50016E-12A) to compose the test reagent cartridge;
4.1.2 Open the seal plug of the sample loading hole, add 350μL sample or SARS-CoV-2-Flu-RSV-Positive Control or SARS-CoV-2-Flu-RSV-Negative Control into the sample loading hole (To ensure Diagnostic System have 300uL samples for nucleic acid extraction); or use transfer pipet from the extraction reagent kit to pipette sample into the sample loading hole (When sample enter the lower bubble of transfer pipet indicates enough sample has been taken). Then close the seal plug.

4.2 Test Procedure

4.2.1 Click the "Specimen" button on the instrument display screen to open the door of the instrument and enter the new experiment task setting interface.
4.2.2 Put the prepared consumables into the designated position of the instrument.
4.2.3 Enter specimen information, select the required experimental project in the drop-down menu of Experimental project, enter the corresponding task name in the Task Name bar, and input and select other items that should be input or selected.
4.2.4 Click "Submit" to submit the experimental task and "OK" to run the instrument.

Reading test results

1. Result Analysis (Refer to user manual of instrument to adjust the settings.)
Results will be saved automatically when reactions are completed. Analyze amplification curve of target of detection and internal control. Adjust Start, End and Threshold values of Baseline of the graph according to analysis result (Users can adjust the values according to the actual situation. Start value can be set between 3-15, and End value between 5-20. Adjust the amplification curve of negative control to be flat or below threshold). Click “Analysis” to implement the analysis, make sure each parameter satisfies the requirements given in “**2. Quality Control**”. Go to “Plate” window to record qualitative results.

2.Quality Control

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. The following describes the result interpretation concerning the use of the controls mentioned above.The Ct cutoff value of this kit is set as 40 and the end user is required to review fluorescent curves before final interpretation. For weakly positive samples, all positive curves are typical S-shaped amplification curves or platform-free periods.
2.1 SARS-CoV-2-Flu-RSV-Negative control: The FAM, HEX/VIC, ROX and internal control (CY5) channels are negative, No Ct or Ct > 40.
2.2 SARS-CoV-2-Flu-RSV-Positive control: The FAM, HEX/VIC, ROX and internal control (CY5) channels have the typial S-shaped amplification curve, the Ct ≤ 35.
2.3 The test result is treated as valid if all the conditions in the above-mentioned are met for the same test. Otherwise the test result is treated as invalid and needs to be re-tested.
Note: Result of (-): Ct value >40 or Undetermined; Result of (+): Ct value ≤ 40.
If there is contamination for the re-run, please perform decontamination procedures.

Reference Range

Through the research on reference values, the Ct reference value of target gene is determined to be 40, the Ct reference value of internal control is determined to be 40.

Interpretation of test results

Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.The end user is required to review fluorescent curves before final interpretation. For weakly positive samples, all positive curves are typical S-shaped amplification curves or platform-free periods(38≤Ct≤40).
1. For samples with a typical S-shaped amplification curve detected in the FAM channel and Ct≤40, it means that the result of SARS-CoV-2 Virus test was positive; For samples with no typical S-shaped amplification curve detected in FAM channel or with Ct > 40, the CY5 channel has an amplification curve and Ct≤40, it means that the result of SARS-CoV-2 Virus test was negative.
2. For samples with a typical S-shaped amplification curve detected in the HEX/VIC channel and Ct≤40, it means that the result of Flu test was positive; For samples with no typical S-shaped amplification curve detected in HEX/VIC channel or with Ct > 40, the CY5 channel has an amplification curve and Ct≤40, it means that the result of Flu test was negative.
3. For samples with a typical S-shaped amplification curve detected in the ROX channel and Ct≤40, it means that the result of RSV test was positive; For samples with no typical S-shaped amplification curve detected in ROX channel or with Ct > 40, the CY5 channel has an amplification curve and Ct≤40, it means that the result of RSV test was negative.
4. For FAM ,HEX/VIC, ROX, and CY5 channels, no typical S-shaped amplification curve (No Ct) is detected, or Ct>40, which means that the cell content of the test sample is too low or there is an interference substance that inhibits the reaction. The test of this sample if the result is invalid, the reason should be found and eliminated, and the sample should be re-sampled for repeated tests (if the test results of the repeated tests are still invalid, please contact our company).
Result of (-): Ct value >40 or Undetermined; Result of (+): Ct value ≤ 40. If the retest is contaminated, please carry out purification treatment.
For technical assistance of test results, please contact local distributor or email: info@sansure.com.cn.

Limitations of the procedure

1. False negative results can be caused by poor specimen quality, improper sample collection, improper transportation, improper laboratory processing, or a limitation of the testing technology.
2. Mutation in the target sequence of SARS-CoV-2, Flu and RSV or change in the sequence due to virus evolution may lead to false negative results.
3. Improper reagent storage may lead to false negative results.
4. Use of this assay is limited to personnel who are trained in the procedure.
5. Test results of the diagnostic kit can only be used as an aid in clinical diagnosis. Symptoms and physical signs, disease history, other laboratory examinations and therapeutic reactions of the patients should be comprehensively considered for the clinical diagnosis and treatment.
6. Unverified interfering substances or PCR inhibitors may lead to false negative or invalid results.

Performance characteristics

1. Inclusivity

Based on the specific sequences of SARS-CoV-2, Flu and RSV retrieved from NCBI database, comparative analysis of computational sequences was conducted for the inclusion of primers/probes used in the Kit . The comparative analysis showed that the target sequences of SARS-CoV-2, Flu and RSV from different sources and different strains had 100% homology.

2. Specificity

There was also no cross-reaction with common respiratory pathogens (The positive specimen of coronavirus (NL63, HKU1, 229E,OC43), MERS coronavirus, adenovirus 1, Human Metapneumovirus, Enterovirus (EV-C95), Rhinovirus, *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Legionella pneumophila*, *Mycobacterium tuberculosis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Bordetella pertussis*, *Mycoplasma pneumoniae*, *Pneumocystis jiroveci Pneumonia*(PJP)).

3. Limit of detection

The limit of detection of this kit is 500 copies/mL.

4. Precision

The coefficient of variation (CV%) of Ct value of the within-run precision is ≤ 5%.

5. Possible interfering substances in specimens

Mucin: bovine submaxillary gland, type I-S (20 μg/mL), Blood (human, 5% (v/v)), Nasal sprays or drops (100μg/mL), Nasal corticosteroids (50 μg/mL), FluMist (100 μg/mL), Homeopathic allergy relief medicine (200 μg/mL), Anti-viral drugs (300 U/MI), Antibiotic, nasal ointment (100 μg/mL), Antibacterial, systemic (100 μg/mL) have no significant interference with the detection results of the kit.

List of references

1. Persistent Detection and Infectious Potential of SARS-CoV-2 Virus in Clinical Specimens from COVID-19 Patients. Viruses. 2020.
2. SARS-CoV-2 host diversity: An update of natural infections and experimental evidence. J Microbiol Immunol Infect. 2021.
3. Advances in research on ACE2 as a receptor for 2019-nCoV. Cell Mol Life Sci. 2021.
4. The Structure, Function, and Pathobiology of the Influenza A and B Virus Ion Channels. Cold Spring Harb Perspect Med. 2020.
5. Pandemic and Avian Influenza A Viruses in Humans: Epidemiology, Virology, Clinical Characteristics, and Treatment Strategy. Clin Chest Med. 2017.
6. Fatal influenza B infections: time to reexamine influenza research priorities. J Infect Dis. 2012 Mar 15;205(6):870-2.
7. Rapid and simple molecular tests for the detection of respiratory syncytial virus: a review. Expert Rev Mol Diagn. 2018.

Symbol key

Symbols	Meanings	Symbols	Meanings
IVD	*In Vitro* Diagnostic Medical Device	LOT	Batch Code
	Use-by date	REF	Reference Number
	Manufacturer		Date of Manufacture
Σ	Contains sufficient for <n> tests		Temperature Limit
	Caution		Consult Instructions for Use
21 PAP	PAP21: Not corrugated cardboard		Do not re-use
EC REP	Authorized representative in the European Community	CE	This product fulfills the requirements of the European Directive 98/79/EC for *in vitro* diagnostic medical devices.
PCR MIX	PCR Mix	ENZYME MIX	Enzyme Mix
CONTROL -	Negative Control	CONTROL +	Positive Control
PRE	Prepackaging		Keep away from light
VERSION	Version	UDI	Unique device identifier

Contact information

Sansure Biotech Inc.
Add: No. 680, Lusong Road, Yuelu District, 410205 Changsha, Hunan Province, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-731-88883176
Fax: +86-731-88884876
Web: www.sansureglobal.com

Obelis s.a.
Bd. Général Wahis 53, 1030 Brussels, BELGIUM
Tel: + (32) 2.732.59.54
Fax: + (32) 2.732.60.03
E-Mail : mail@obelis.net

CE IVD