Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

Product Identification

Product Name: Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

Reference Number: S3102E

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

Intended Use

Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is used for qualitative detection of the ORF1ab and N genes of novel coronavirus (2019-nCoV) in nasopharyngeal swab, oropharyngeal swab, alveolar lavage fluid, sputum, serum, whole blood, feces from suspected pneumonia cases with novel coronavirus infection, in patients with suspected clusters of novel coronavirus infection, and other patients requiring diagnosis or differential diagnosis of novel coronavirus infection[1].

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

Test principle summary and explanation

Summary

The novel virus, now known as SARS-CoV-2 (previously known as 2019-nCoV), is a RNA virus of the beta coronavirus family.It's demonstrated that SARS-CoV-2 has the capability to spread rapidly, leading to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by SARS-CoV-2 is globally high.

The first symptoms of the SARS-CoV-2 are not very specific. People may experience runny nose, headache, muscle pain and tiredness. Fever, cough and respiratory signs often occur 2 or 3 days later and can lead to severe pneumonia and death[2]. The severity of clinical signs requires that approximately 20% of patients remain in hospital and 5% require admission to intensive care. The most serious forms are observed mainly in people who are vulnerable because of their age (over 70) or associated diseases. However, the infection can also be asymptomatic or paucisymptomatic (i.e., causing little or no clinical manifestations) in 30% to 60% of infected subjects. The duration of incubation is on average 5 days, with extremes of 2 to 14 days. The serial interval (i.e., time between one person developing symptoms of a disease and a second person becoming infected and developing symptoms) is approximately 4 days. Thus, the serial interval of SARS-CoV-2 is shorter than its median incubation period. This suggests that a substantial proportion of secondary transmission may occur prior to illness onset. This "silent transmission" makes this pandemic hard to contain and more likely to spread very quickly.

Laboratories are required to report all positive results to the appropriate public health authorities. Negative results do not preclude novel coronavirus (2019-nCoV) infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Test Principle

By applying Real-time fluorescence quantitative RT-PCR technology on the fluorescence quantitative PCR instrument, this test utilizes the novel coronavirus (2019-nCoV) *ORF 1ab* and the specific sequence of coding nucleocapsid protein *N* gene as the target regions which are designed for the conserved sequence of the double-target genes, to achieve detection of sample RNA through fluorescent signal changes.

The PCR detection system uses a positive internal control, which monitors the presence of PCR inhibitors in test specimens , to avoid a false negative result.

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	2019-nCoV-PCR Mix	624 μL/tube × 1 tube	1248 μL/tube × 1 tube	26 μL/tube × 24 tubes	26 μL/tube x 12 tubes	Primer, Probes, dNTPs, $MgCl_2$, Rnasin, PCR buffer
2	2019-nCoV-PCR-Enzyme Mix	96 μL/tube ×1 tube	192 μL/tube × 1 tube	4 μL/tube × 24 tubes	4 μL/tube x 12 tubes	RT Enzyme, Taq Polymerase
3	2019-nCoV-PCR-Positive Control	500 μL/tube ×1 tube	500 μL/tube × 1 tube	500 μL/tube × 1 tube	500 μL/tube x 1 tube	In vitro transcriptional RNA containing target genes (*ORF1ab*, *N* gene) and internal standard gene fragments (*Rnase P*)
4	2019-nCoV-PCR-Negative Control	500 μL/tube × 1 tube	500 μL/tube × 1 tube	500 μL/tube × 1 tube	500 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 centrifuge tubes, 0.2 mL PCR reaction tubes, pipette tips (10 μL, 200 μL and 1000 μL tips with filters are preferred), desktop centrifuge, desktop vortex mixer various models of pipettes.
2. Not included in the kit reagent: Sample Release Reagent (Reference Number: S1014E Series) or Sample Release Reagent (Reference Number: S1015E Series) or Nucleic Acid (DNA/RNA) Extraction or Purification Kit (Magnetic beads method) (Reference Number: S1002E Series) or Multi-type Sample DNA/RNA Extraction-Purification Kit (Magnetic beads method) (Reference Number:S1006E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S10015E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S10016E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S50016E Series) or Nucleic Acid Extraction-Purification Kit(Reference Number: S10018E Series) manufactured by Sansure Biotech Inc. or QIAamp Viral RNA Mini Kit (50) manufactured by QIAGEN. Sample Storage Reagent (Reference Number: X1002E Series, X1003E Series, X1004E Series, X1010E Series and X1011E 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 18 months at -25° C to -15° C and protected from light.
2. Please refer to the date of manufacture and expiry date on the outer package.
3. The reagents keep valid and stable within the expiry date if not used. As long as the container of the reagent is opened, the freeze/thaw cycles should not exceed three.

Instrumentation

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

1. Angilent/AriaDx Real-Time PCR System
2. Applied Biosystems/7500 Real-Time PCR System
3. Bioer/QuantGene 9600 Fluorescent Quantitative Detection System (Model: S-Q96C)
4. Bio-Rad/CFX96 Dx and CFX96 Deepwell Dx Systems
5. Hongshi/SLAN®-96P Real-Time PCR System
6. Molarray/Real-Time Quantitative Thermal Cycler (Model: MA-6000)
7. Roche/cobas z 480 analyzer
8. Roche/LightCycler® 480 instrument II
9. Sansure/Portable Molecular Diagnostic System (S-Q37A/S-Q37B)
10. Sansure/Portable Molecular Workstation (Model: S-Q36A)
11. Sansure /Portable Molecule Workstation (Model: S-Q31A/S-Q31B)
12. Thermofisher/QuantStudio™ 5 Real-Time PCR System

Collecting and preparing specimens

1. Applicable sample type: nasopharyngeal swab, oropharyngeal swab, alveolar lavage fluid, sputum, serum, whole blood, feces.
2. Collection of sample

Nasopharyngeal swab/oropharyngeal swab: Collect sample in accordance with the relevant provisions of "Specimen Collection Method" in the "Technical Guidelines for COVID 19 Laboratory Testing". It is proved that the swab made of nylon sampling head and ABS sampling rod can be used for sample collection.

Nasopharyngeal swab: The sample 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 15-30 s, gently rotate 3-5 times, quickly put swab into sample collection tube cotaining 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 sample 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 and avoid touching the tongue. Quickly place a sterile swab into the collection tube used for collection of oropharyngeal swab. Break the sterile swab rod near the top, tighten tube cap and seal with sealing film.

Alveolar lavage fluid: Severe patients or patients with pneumonia who progress rapidly. Clinician extracts ≥5 ml BALF into a 50 mL aseptic container labeled with sample bar code and screw cap by aseptic operation. Collect sample, then tighten tube cap and seal with sealing film.

Sputum: The sample collection tube should be pasted with the barcode first. Do not open the respiratory tract to collect samples when collecting sputum. Collect.deep cough sputum into a disposable aseptic sampling cup with screw cap, and load 2 mL protease K (1g/L) into sampling cup. Collect sputum, then tighten tube cap and seal with sealing film. Send to detection within 30 min as far as possible. Protease K should not be added first if samples need to be transported over long distances.

Whole blood: Blood samples can be collected within 7 days after the onset or from critical patients, or patients considered with viremia. The sample collection tube should be pasted with the barcode first. Collect 2-4 mL of blood samples into vacuum blood collection tube containing EDTA anticoagulant.

Feces: For patients with gastrointestinal symptoms such as diarrhea at the early stage of the disease, preserve 3-5 g (soybean size) feces. The sample collection tube should be pasted with the barcode first. Collect sample into sample collection tube with screw cap cotaining 2 mL normal saline (RNA enzyme inhibitor can be added when conditions permit) then seal with sealing film. After sample collection, it is recommended to place into Sample Storage Reagent for preservation.

It has been proved that preservation solution, such as normal saline, TE buffer, 2-4M containing guanidine (such as guanidine hydrochloride) can also be used as Sample Storage Reagent for sample preservation.The Sample Storage Reagent containing guanidine cannot be directly adapted to Sample Release Reagent manufactured by Sansure Biotech Inc. for nucleic acid extraction. If necessary, it is recommended to use Nucleic Acid (DNA/RNA) Extraction or Purification Kit (Magnetic beads method) (Reference Number: S1002E Series) or Multi-type Sample DNA/RNA Extraction-Purification Kit (Magnetic beads method) (Reference Number: S1006E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S10015E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S10016E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S50016E Series) or Nucleic Acid Extraction-Purification Kit(Reference Number: S10018E Series)manufactured by Sansure Biotech Inc.or the QIAamp Viral RNA Mini Kit (50) manufactured by QIAGEN for nucleic acid extraction.

3. Storage and delivery of samples:

Samples to be tested can be immediately processed, samples to be tested within 24 hours can be stored at 4°C. Samples that cannot be detected within 24 hours should be stored at -70℃ or below (in the absence of -70℃ storage conditions, samples to be tested can be stored at -20°C for 10 days, nucleic acid can be stored at -25°C to -15°C for 15 days). Multiple freeze/thaw cycles should be avoided. Samples should be transported in a sealed frozen pitcher with ice or in a sealed foam box with ice. The inactivation of samples at 56°C for 30min will not affect the detection of this kit.

Test procedure

1. Please process according to the following steps forSLAN®-96P Real-Time PCR System, 7500 Real-Time PCR System, QuantStudio™ 5 Real-Time PCR System, cobas z 480 analyzer,Real-Time Quantitative Thermal Cycler (Model: MA-6000), CFX96 Dx and CFX96 Deepwell Dx Systems, QuantGene 9600 Fluorescent Quantitative Detection System (Model: S-Q96C) instrument:

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

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

1.1.2 According to the quantity of test samples, 2019-nCoV-PCR-Positive Control and 2019-nCoV-PCR-Negative Control, pipette appropriate quantity of 2019-nCoV-PCR Mix and 2019-nCoV-PCR-Enzyme Mix (2019-nCoV-PCR Mix 26 μL/test + 2019-nCoV-PCR-Enzyme Mix 4 μL/test), mix them thoroughly to make a PCR-Mastermix, centrifuge it instantaneously for later use.

	1 sample	10 samples	24 samples	48 samples
2019-nCoV-PCR Mix (μL)	26	260	624	1248
2019-nCoV-PCR-Enzyme Mix (μL)	4	40	96	192

Note: The above configuration is just for your reference and to ensure enough volume of the PCR-Mastermix, more volume may be required.

1.1.3 Transfer the above-prepared reagents to the "sample processing room" for later use.

1.2. Processing and loading of samples (performed at "sample processing room")

1.2.1 Use Sample Release Reagent (Reference Number: S1014E Series), Sample Release Reagent (Reference Number: S1015E Series), Nucleic Acid (DNA/RNA) Extraction or Purification Kit (Magnetic beads method) (Reference Number: S1002E Series) or Multi-type Sample DNA/RNA Extraction-Purification Kit (Magnetic beads method) (Reference Number: S1006E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S10015E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S10016E Series) or Nucleic Acid Extraction-Purification Kit (Reference Number: S50016E Series) or Nucleic Acid Extraction-Purification Kit(Reference Number: S10018E Series)manufactured by Sansure Biotech Inc. to extract the nucleic acid as per product manual.

1.2.2 Add 30 μL PCR-Mastermix into PCR reaction tube with 20 μL above processed sample. Carry out fluorescence quantitative PCR detection on fluorescence PCR instrument. The fluorescent PCR tube can be sealed with 15 μL paraffin oil before PCR amplification.

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

1.3.1 Place PCR reaction tubes into the sample wells of the amplification equipment. Set up the 2019-nCoV-PCR-Positive Control, 2019-nCoV-PCR-Negative Control and samples to be tested in the corresponding sequence and input sample name.

1.3.2 Select PCR test channel:

a) Select FAM (*ORF1ab* gene) and ROX (*N* gene) channels to test 2019-nCoV nucleic acid.

b) Select CY5 channel to test internal control.

1.3.3 Set cycle parameters

	Steps	Temperature	Time	Cycle No.
1	Reverse transcription	50°C	30 min.	1
2	cDNA predenaturation	95°C	1 min.	1
3	Denaturation	95°C	15 sec.	45
	Annealing, extension and fluorescence detection	60°C	30 sec.	
4	Device cooling	25°C	10 sec.	1

1.3.4 Some PCR instrument (such as SLAN®-96P, Life Technologies QuantStudio ™ 5 , MA-6000, CFX96) can set a faster PCR amplification program and set cycle parameters as follow:

	Steps	Temperature	Time	Cycle No.
1	Reverse transcription	50°C	3 min.	1
2	cDNA predenaturation	95°C	5 sec.	1

3	Denaturation	95°C	5 sec.	41
	Annealing, extension and fluorescence detection	60°C	16 sec.	
4	Device cooling	25°C	10 sec.	1

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

(1) Take out the reaction tube carrier, PCR reaction tube and Tip.

(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.)

(3) Put Sample Release Reagent (Reference Number:S1014E Series or Reference Number:S1015E Series) into the **Well** B; Put 2019-nCoV-PCR Mix into the **Well** C; Put 2019-nCoV-PCR-Enzyme Mix into the **Well** D;

(4) Add 20μL sample to be tested or 2019-nCoV-PCR-Positive Control or 2019-nCoV-PCR-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 Gently 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.

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

2.2.4 Select the required experimental 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 experimental task and "**OK**" to run the instrument and start the experimental 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

(1) Take out the Consumables kits and reagents.

(2) Put Sample Release Reagent (Reference Number:S1014E Series or Reference Number:S1015E Series) into the **Well** B; Put 2019-nCoV-PCR Mix into the **Well** C; Put 2019-nCoV-PCR-Enzyme Mix into the **Well** D (The well location information has been marked on the carrier set).

(3) Add 20μL sample to be tested or 2019-nCoV-PCR-Positive Control or 2019-nCoV-PCR-Negative Control into the **Well** B (To avoid bubbles during operation, it is recommended to pipet deeply and release slowly).

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

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 required experimental 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 experimental task and "**OK**" to run the instrument and start the experimental 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 2019-nCoV-PCR-Positive Control or 2019-nCoV-PCR-Negative Control into the sample loading hole (To ensure Diagnostic System have 300μL 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 satisfy the requirements given in "5. Quality Control". Go to "Plate" window to record qualitative results.

2. Quality Control

	2019-nCoV-PCR-Negative Control	2019-nCoV-PCR-Positive Control
Ct value	No Ct or Ct > 40 at channel FAM, ROX and CY5 (internal control)	≤ 35 at channel FAM, ROX and CY5 (internal control)

The test result is treated as valid when 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.

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

Conclusion	Amplification results
2019-nCoV Positive	There is typical S-shape amplification curve detected at FAM and/or ROX channel, and the amplification curve which is detected at CY5 channel, Ct≤40.
2019-nCoV Negative	There is no typical S-shape amplification curve(No Ct) or Ct＞40 detected at FAM and ROX channel, and the amplification curve which is detected at CY5 channel, Ct ≤ 40.

There is no typical S-shape amplification curve detected at FAM, ROX and CY5 channel (No Ct), or Ct > 40. It is indicated that the sample' s concentration is too low, or there are interfering substances that inhibit the reaction. The test result is invalid. An investigation should be performed to find out and exclude the reasons, please collect sample again and retest the samples. (If repeated tests still produce invalid results, please contact Sansure Biotech.)

Note: For virus cultures, there is no requirements for internal control test results.

Limitations of the procedure

1. Test results of the kit can be used only for clinical reference. The symptoms and physical signs, disease history, other laboratory examinations and therapeutic reactions of the patients should be comprehensively considered during their clinical diagnosis and treatment.

2.The possible reasons for false negative results:

2.1 The unsuitable collection of specimen, delivery, processing and sample in low concentrations may lead to false negative results.

2.2 A mutation in the target sequence of 2019-nCoV novel coronavirus to be measured or a change in the sequence due to other causes may lead to false negative results.

2.3 The unreasonable storage of reagent may lead to false negative results.

2.4 Unverified interferences or PCR inhibitors may lead to false negative results.

2.5 Cross-contamination occurring in the sample processing may lead to false positive results.

2.6 The clinical laboratory should be equipped with instruments and operators in strict accordance with relevant requirements outlined in local, state and national regulations. Operate in strict accordance with the product manual.

Performance characteristics

1. Accuracy

When testing the enterprise positive reference, all results are positive.

2. Specificity

For Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing), there are also no cross-reaction with coronavirus (NL63, HKU1, 229E,OC43), SARS coronavirus, MERS coronavirus, influenza A virus, influenza B virus Type Yamagata and Type Victoria, influenza A (H1N1) virus, influenza A (H3N2) virus, influenza A (H5N1) virus, influenza A (H7N9) virus, respiratory syncytial virus type A and Type B, nasal virus Type A, Type B and Type C, adenovirus Type 1, 2, 3, 4, 5, 7 and 55, parainfluenza virus Type 1, 2 and 3, intestinal virus type A, type B, type C (EV-C95), type D(EV-D70), Human metapneumovirus, *cryptococcus neoformans, pyogenic streptococcus, acinetobacter baumannii, pnes*pecimen*umocystis carinii, klebsiella pneumoniae, streptococcus pneumoniae, haemophilus influenzae, pseudomonas aeruginosa, legionella pneumophilia, bordetella pertussis, staphylococcus aureus, mycoplasma pneumoniae pneumonia, chlamydia,* EB virus, human cytomegalo virus, *aspergillus fumigatus, candida albicans, candida glabrata, mycobacterium tuberculosis, non-tuberculous mycobacterium,* norovirus, rotavirus, varicella zoster virus, measles virus, mumps virus, human genome DNA samples. When testing the enterprise negative reference, all result are negative.

3. **Limit of detection:** The limit of detection of this kit is 200 copies/mL.

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

5. **Possible interfering substances in samples:** 100 μg/mL hydroxymezoline hydrochloride, 50 μg/mL dexamethasone, 50 μg/mL cefmenoxime hydrochloride, 100 μg/mL oseltamivir, 100 μg/mL zanamivir, 100 μg/mL ribavirin, 100 μg/mL azithromycin, 300U/mL α-interferon, 320 μg/mL budesonide, 125 μg/mL beniferin, 100 μg/mL tobramycin, 50 μg/mL beclometrasone, 100 μg/mL flunicasone, 100 μg/mL momethasone, 200 μg/mL fluticasone, 200 μg/mL histamine dihydrochloride, 100 μg/mL peramivir, 100 μg/mL lopenavir, 100 μg/mL mupiroxacin, 100 μg/mL triamcinolone, 100 μg/mL litonavir, 100 μg/mL abidor, 60 μg/mL sodium chloride, 100 μg/mL urea, 10 μg/mL heme, 20 μg/mL purified mucin, 20%(v/v) anhydrous ethanol, and 20%(v/v) human whole blood have no significant interference with the detection results of the kit.

6. **Clinical evaluation:** The total sensitivity: 99.48 % (95%CI: 97.1%-100.0 %), specificity: 100 % (95%CI: 99.2%-100.00%), total compliance rate: 99.84 % (95%CI: 99.1%-100.00 %), and Kappa value: 0.9963.

List of references

1. Coronavirus Causes Lower Respiratory Tract Infections Less Frequently Than RSV in Hospitalized Norwegian Children. The Pediatric Infectious Disease Journal, 2010.

2. A novel pancoronavirus RT-PCR assay: frequent detection of human coronavirus NL63 in children hospitalized with respiratory tract infections in Belgium. BMC Infectious Diseases, 2005.

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
PCR MIX	PCR Mix	ENZYME MIX	Enzyme Mix
CONTROL -	Negative Control	CONTROL +	Positive Control
PRE	Prepackaging		Keep away from light
EC REP	Authorized representative in the European Community	VERSION	Version
UDI	Unique device identifier	CE	This product fulfills the requirements of the European Directive 98/79/EC for *in vitro* diagnostic medical devices.

Contact information

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