For In Vitro Diagnostic Use Only

For Prescription Use Only

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Severe Acute Respiratory Syndrome Novel Coronavirus (COVID-19) Nucleic Acid Assay Kit (Isothermal Amplification Fluorescence Method)

INTENT OF USE

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Nucleic Acid Detection Kit（Isothermal Amplification Fluorescence Method） is a qualitative nucleic acid in vitro amplification testing kit for the detection of N gene in severe acute respiratory syndrome coronavirus 2. The kit uses nasal swabs, nasopharyngeal aspirates, deep sputum, bronchoalveolar lavage fluid or blood samples from suspected cases with novel coronavirus pneumonia or other patients who need to be tested.

PRINCIPLE OF THE TEST

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Nucleic Acid Detection Kit（Isothermal Amplification Fluorescence Method） is a qualitative nucleic acid in vitro amplification testing kit for the detection of N gene in severe acute respiratory syndrome coronavirus 2 by loop mediated isothermal amplification (LAMP). The reaction system contains a kind of fluorochrome, which can bind to double strands of DNA. following amplification, N gene in severe acute respiratory syndrome coronavirus 2 can be increased exponentially in the detection, the fluorescence is measured during this process by instrument

APPLICABLE INSTRUMENT

For use with ABI 7500/Quantstudio3/Quantstudio5/Quantstudio6; Roche LightCycler480; Bio-Rad CFX96.

REAGENTS AND MATERIALS SUPPLIED

50-Test Kit:

- Buffer (960μL/Tube, 1 Tube): Primers, dNTPs, Buffer, etc.
- DNA Polymerase (55μL/Tube, 1 Tube): BST DNA Polymerase
- AMV Reverse Transcriptase (5μL/Tube): AMV Reverse Transcriptase
- Sealing Fluid (1.4mL/Tube, 1 Tube): Oil
- Positive Control (50μL/Tube, 1 Tube): Plasmid Containing Target Gene
- Negative Control (50μL/tube, 1 Tube): Water

***Note: All components can only be used within the same LOT.**

**All components are to be taken out immediately before use, thawed and used following centrifugation. Immediately after use, store at -20 ℃.

KIT STORAGE AND STABILITY

- Store in dark at -20℃±5℃ for 6 months. cold transportation with ice bags in 4 days. avoid repeated thawing and freezing of the reagents, and the number shall not exceed 10.
- Production date: see label.
- Expiration date: see label.

REQUIREMENTS FOR SAMPLES

1. Sample types include: upper respiratory tract samples (including throat swab, nose swab, nasopharynx extract, deep expectoration fluid), alveolar lavage fluid and blood.
2. For the sample collection, please refer to the manual of microbial sample collection.
3. After sample collection, the test shall be completed on the same day. Otherwise, it shall be stored at 2℃-8℃ in less than 24 hours or -20℃ for no more than 3 months.

TEST PROCEDURE

1. RNA Extraction

Use virus RNA Extraction Kit with FDA approved to extract nucleic acid.

2. Reagent Preparation

Throw the reagents, vortex and centrifuge briefly the tubes. According to the number of samples tested, prepare the reaction solution according to the following table. It is recommended to set negative control and positive control for each test.

Reaction Liquid Components	Added Amount(μL)/Per Person
Buffer	18.9
DNA Polymerase	1.0
AMV Reverse Transcriptase	0.1
Total	20.0

After the reaction solution is well mixed, it is split into the PCR reaction tube according to the amount of 20μL.

3. Sample Adding

Add 5μL of negative control, sample nucleic acid extract and positive control to different tubes respectively, the final volume is 25μL/tube, then add 25μL of sealing liquid respectively, cover the reaction tube tightly, centrifugate instantaneously at low speed.

4. Detection

Turn on the instrument, put the reaction tubes into the instrument, and select the testing type according to the following table

Applicable Instrument	Detection Type
ABI 7500 / Quantstudio3 / Quantstudio5 / Quantstudio6; Roche LightCycler480; Bio-Rad CFX96.	Quantitation-Standard Curve or Isothermal

Perform the following protocol in the instrument. If you use ABI instrument, please choose "none" as passive reference and quencher.

Step Number	Temperature	Time	Fluorescence Signal Acquisition (FAM)	Cycle Number
1	63℃	60s	Yes	30

5. *Result Analysis (refer to ABI 7500 for example)*

After the reaction, the results are saved automatically, and the baseline start point, baseline end point and threshold are adjusted according to the analyzed image. The baseline start point can be 2-3, the baseline end point can be set at 4-6 (can`t be larger than the Ct value of Positive samples and positive control) according to the actual situation, the threshold line is located in the exponential period of the amplification curve, and the automatic threshold setting can also be used. Click "Reanalyze" to automatically analyze the results, and read the test results in the "View Plate Layout" or "View Well Table" interface.

INTERPRETATION OF RESULTS

1. Quality control standard

The Ct value of the PC should be less than 15 and there should be a specific amplification curve. The NC should have no Ct value and no specific amplification curve. The experimental results are valid if the above criteria are met. Otherwise, the test should be carried out again.

2. Determination of test results

1) Positive: If the Ct value is less than or equal to 25 and there is a specific amplification curve, it is judged as positive;
2) Negative: No Ct value was found in the tested sample, which was negative;
3) Suspicious: If 25 < Ct value ⩽ 30 and there is a specific amplification curve, it shall be determined as a suspicious sample, which shall be reextracted and tested again.

LIMITATIONS

1. Negative results can not completely exclude pathogen infection, the concentration of target gene in the sample is lower than the detection limit or the mutation of target sequence can also cause negative results.
2. Unreasonable sample collection, transfer and treatment, improper test operation and test environment may lead to false negative or false positive results.
3. The test results of this product are only for clinical reference and should not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in combination with their symptoms / signs, medical history, other laboratory tests and treatment reactions.

PERFORMANCE CHARACTERISTICS

1. The minimum detection amount: 1000 Copies/mL.
2. Specificity: There was no nonspecific amplification of Human Coronavirus OC43, Human Coronavirus HKU1, Human Coronavirus 229E, Human Coronavirus NL63, Adenovirus, Respiratory Syncytial Virus A, Human Parainfluenza 2, Human Parainfluenza 3, H1N1, H5N1, H7N9, H9N2, Mycoplasma pneumoniae and Influenza B virus.
3. Precision: two cases of high and low concentration positive control samples were tested 10 times repeatedly, and the CV of Ct value was ⩽20%.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. This assay needs to be carried out by skilled personnel.
3. The assay needs to be run according to Good Laboratory Practice.
4. The laboratory is divided into three areas for operation (reagent preparation area, sample preparation area and amplification area).
5. The reagents should be vortex and centrifuge briefly before use.
6. Always sterile pipette tips with filters.
7. The pipets, vials and other materials shall be regarded as infectious substances, and the operation and treatment shall meet the requirements of relevant laws and regulations.

REFERENCE

Hui, D. S., I Azhar, E., et.al (2020). The continuing 2019-nCoV epidemic threat of novel coronaviruses to global health-The latest 2019 novel coronavirus outbreak in Wuhan, China. International Journal of Infectious Diseases, 91, 264–266.

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ISO 15223 Symbols	
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device
	Read instructions for use
	Use by
	Do not re-use
	Do not use if package is damaged
	Temperature limit
	Keep away from sunlight
Σ	Contains sufficient for <n> tests
EC REP	Authorized Representative in the European Community / European Union
LOT	Batch code
REF	Catalog number
IVD	In vitro diagnostic medical
SN	Serial number
	Biological risks
	Manufacturer
	Date of manufacture
	Caution