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SARS-CoV-2 Rapid Detection Kit (RT-PCR)Instructions for Use

Only for Professional use in In-Vitro Diagnostics

Product Name

SARS-CoV-2 Rapid Detection Kit (RT-PCR)

Package Specifications

16 Tests/Kit, 32 Tests/Kit, 48 Tests/Kit, 96 Tests/Kit

Intended use

This product is used to qualitatively detect suspected cases of pneumonia with novel coronavirus infections, suspected cluster cases and other throat swabs and nasal swabs that require diagnosis or differential diagnosis of novel coronavirus infections in novel coronavirus (SARS-CoV-2) RdRp genes and N genes.

Infection with novel coronaviruses can cause acute infectious pneumonia, and common signs of coronavirus infection in humans include respiratory symptoms, fever, cough, and shortness of breath. In more severe cases, the infection can lead to pneumonia, severe acute respiratory syndrome, kidney failure, and even death. .

Currently, there is no specific treatment for diseases caused by novel coronaviruses. Laboratory personnel should receive professional training in gene amplification or molecular biology testing and have the appropriate experimental qualifications, and laboratories should have adequate biosecurity facilities and protective procedures.

When tested with this kit, negative results cannot rule out infection with novel coronaviruses and cannot be used as the sole basis for diagnostic,treatment or other management decisions, and positive results cannot rule out bacterial infections or other viral infections.

Test principle

This product is released by highly efficient nucleic acids and is tested for nucleic acids using fluorescent RT-PCR probes. By comparing the similarities and differences between the RdRp and N genes between the strains of coronaviruses, specific primer probes are designed.

At the same time, the human RNaseP gene sequence is used as a template to design the primer probe as an internal control index. Among them, the novel coronavirus SARS-CoV-2 specific probe RdRp gene marker FAM fluorescence, N-gene marker HEX fluorescence, internally controlled gene marker ROX fluorescence.

Constituents

The components of the kit are listed in the following table:

Series-No.	Label	16 Tests/Kit	32 Tests/Kit	48 Tests/Kit	96 Tests/Kit
1	SARS-CoV-2 Reaction vessel	16 Tubes	32 Tubes	48 Tubes	96 Tubes
2	SARS-CoV-2 Lysis solution	16 Tubes (1mL/tube)	32 Tubes (1mL/tube)	48 Tubes (1mL/tube)	96 Tubes (1mL/tube)
3	SARS-CoV-2 Negative Control	1 Tube (0,5mL/tube)	1 Tube (0,5mL/tube)	1 Tube (0,5mL/tube)	1 Tube (0,5mL/tube)
4	SARS-CoV-2 Positive Control	1 Tube	1 Tube	1 Tube	1 Tube
5	Disposable bags	16	32	48	96
6	Instructions for use	1	1	1	1

Storage conditions and expiry date

All reagents should be stored at 2°C~8°C away from light and are valid for 6 months.

SARS-CoV-2 positive control should be stored at -20 ± 5 °C after solution and is valid for 6 months.

If the transport temperature is between 10 °C and 20 °C, the transport time should not exceed 7 days. If the transport temperature is below 10°C, the transport time should not exceed 21 days.

Applicable instruments

Suitable PCR systems

Sample Requirements

1. The sample was taken from a patient with unexplained viral pneumonia or a patient with suspected viral pneumonia;
2. Sample types: Oropharyngeal smears and nasal swabs;
3. Collect samples in "SARS-CoV-2 lysis solution".
4. Storage conditions: Collected samples should be stored in a timely manner for inspection and kept at 4°C within 24 hours of detection.

Test Method

1. Reagent preparation:

1.1 Preparation of the positive control: Give 250μL of the SARS-CoV-2 negative control to the SARS-CoV-2 positive control, then swirl and briefly centrifuge.

1.2 Preparation of the negative control: No special handling

1.3 Sample:

1.3.1 (Option) After sampling, place the sample swab in the tube with the sample lysis solution, shake the tube well and then place the sample swab in the disposable bag;

1.3.2 (Option) If the sample is taken by VTM or another method (not placed in the tube for sample lysis solution), the sample must be nucleic acid purified.

2. Addition of reagents:

2.1 Addition of positive control: pipette 25μL positive control into one of the SARS-CoV-2 reaction tubes using micropipettes with sterile filter tips;

2.2 Addition of negative control: pipette 25μL negative control with the help of micropipettes with sterile filter tips into another of the SARS-CoV-2 reaction tubes;

2.3 Addition of the sample:

2.3.1 (Option) pipette 25μL sample into the remaining SARS-CoV-2 reaction tubes using micropipettes with sterile filter tips;

2.3.2 (Option): Pipette 20 μl of sample lysis solution into the remaining SARS-CoV-2 reaction tubes, then add 5 μl of purified nucleic acid into the same SARS-CoV-2 reaction tubes.

3.Mix reagent

Close the tubes immediately to avoid contamination and briefly tip and shake the reaction tube several times so that the sample and the enzyme ball in the reaction tube completely mix to ensure that the sample completely dissolves the enzyme ball at the bottom of the reaction tube.

4 Mechanical detection (PCR amplification zone).

Insert the PCR reaction vessel into the appropriate PCR system and set the cycle parameters as follows: