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 12 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:

Steps	Stage Name	Number of cycles	Temperature	Reaction time (Min:Sec)
1	Constant Temp Level	1	50℃	08:00
2	Constant Temp Level	1	93℃	01:00
3	Cycle stage	40	93℃/58℃	00:10/00:30
4	Holding level	1	40℃	01:00

The fluorescence signals are captured as FAM (RdRp gene), HEX(N gene) and ROX (internal control), and the data is collected at 58℃.

Explanation of the test results

After the reaction, the device automatically saves the results.

1. Determination of results

Select each fluorescence channel to read the Ct value and determine the result using the following table:

	Ct value		Analysis of results
	FAM	HEX	
1#	>38	>38	SARS-CoV-2 Negative
2#	≤38	≤38	SARS-CoV-2 Positive
3#	≤38	>38	Test again: Report positive as SARS-CoV-2 when channel FAM is still ≤ 38.
4#	>38	≤38	Test again: Report positive as SARS-CoV-2 if channel HEX/VIC/JOE is still ≤38.

2. Quality Control:

In the same experiment, the following conditions must be met at the same time, otherwise the PCR reaction is considered invalid and must be tested again. Here's how:

2.1 The target gene for positive control should have a typical amplification curve and a Ct value ≤35.0;

2.2 The internal control gene of the detection hole should generally have a typical amplification curve and a Ct value ≤38.0;

Limitations of the test method

1. The results of the sample test depend on the quality of sampling, processing, transport and preservation, and any error will result in false negative results.
2. False positive results can occur if cross-contamination is not controlled during sample processing.
3. For kits with inclusions, the amplification of the inner mark may fail if the sample concentration is too high.

Product Performance Indicators

20 repeated test simulation samples show the minimum detection limit for this product: 500 copies/ml sensitivity

Comparative tests of clinical samples show a positive match rate of 100% and a negative match rate of 100%.

Note

1. The entire testing process should be divided into three areas: one area for reagent preparation, two areas for sample treatment, the formulation of the reaction system, three areas for amplification, fluorescence detection and result analysis. Instruments, equipment and workwear are used independently in each area to avoid contamination.

2. During operation, care should always be taken to avoid contamination of RNase and DNase, disposable gloves without fluorescent substances (often replaced), thin-walled 200uL PCR vessels (or 96-hole PCR plate plus optical film), pipette head (with filter dump) should be used, whereby the reaction vessel must not touch directly with the hand.

3. Biosafety cabinets should be used for the treatment of samples to ensure the safety of personnel and to avoid pollution. Dangerous and toxic samples and reagents should be properly placed and stored by specially appointed persons; Instruments such as operator stations, pipettes, centrifuges, amplifiers, etc. should be wiped frequently and disinfected with 1.0% sodium hypochlorite and/or 70% ethanol. The experimental room and the ultra-clean workbench should be treated with a UV lamp regularly and after each experiment.

4. Reagents in the centrifuge tubes should be completely melted, mixed, and centrifuged for a few seconds before use so that the liquid concentrates in the bottom of the centrifugal tube. When formulating the reaction system, please make sure that all liquids should be mixed as much as possible on the vortex mixer, avoiding blowing out with pipette and thereby creating bubbles, and centrifuging at low speed is necessary for a few seconds after the formulation of the reaction system. Kits should be used during shelf life. Reagents with different batch numbers should not be mixed.

5. No partition detection is required when using the Glray Gene Q Series fully automatic fluorescence PCR device. Pay attention to the timely cleaning of medical waste.

Basic information

Distributor: Alpera GmbH
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CE

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Address:	Koningin Julianaplein 10, 1e Verd,2595AA, The Hague, Netherlands.
Tel:	

Description of symbols

IVD	Medical device for in vitro diagnosis		Avoid too much sun exposure
	Follow the instructions for use		Biological risks
	Temperature limit		Expiration date
	Keep dry		Manufacturer
	Manufacture date	EC REP	Authorised representative in the European Community
	Do not reuse		Do not use if the packaging is damaged
	Warning, please refer to the instruction in the annex.	CE	CE mark
LOT	Lot Number		