Fast SARS-CoV-2, Delta & Omicron Variant Detection Kit (Fluorescent RT-PCR)

【Product Name】

Fast SARS-CoV-2, Delta & Omicron Variant Detection Kit (Fluorescent RT-PCR)

【Packaging Specifications】

16 Tests / Box, 24 Tests / Box, 48 Tests / Box, 96 Tests / Box

【Expected Use】

This product is used to qualitatively detect suspected cases of pneumonia with novel coronavirus infections, suspected cluster cases, and other nasopharyngeal swab samples that require diagnosis or differential diagnosis of novel coronavirus infections in novel coronavirus (SARS-CoV-2) RdRp genes and N genes and omicron and delta variant. Novel coronavirus infection can cause acute infectious pneumonia, and common signs of human infection with coronavirus include respiratory symptoms, fever, cough, shortness of breath and difficulty breathing. In more severe cases, infection can lead to pneumonia, severe acute respiratory syndrome, kidney failure, and even death. At present, there is no specific treatment for novel coronavirus-induced diseases. Experimental operators should receive professional training in gene amplification or molecular biology method testing, have relevant experimental operational qualifications, and laboratories should have reasonable biosecurity preparedness facilities and protective procedures. With this kit test, negative results cannot rule out infection with novel coronaviruses, cannot be used as the sole basis for diagnosis, treatment or other management decisions, and positive results cannot exclude bacterial infections or other viral infections.

The SARS-CoV-2 sample added to the Sample preservation fluid containing protectene can be quickly inactivated by protectene in the testing.

【The Principle of Inspection】

This product is released by high-efficiency nucleic acids and is tested for nucleic acids using probe fluorescent RT-PCR. To compare the similarities and differences between the RdRp and N genes between the strains of coronaviruses, and to design specific primer probes. At the same time, the human RNaseP gene sequence is used as the template to design the primer probe as the internal control index. Among them, the novel coronavirus SARS-CoV-2 specific probe RdRp gene and N gene marker FAM fluorescence, internally controlled gene marker VIC fluorescence, Delta variant marker ROX fluorescence, Omicron variant marker CY5 fluorescence.

The SARS-CoV-2 sample added to the Sample preservation fluid containing protectene can be quickly inactivated by protectene, effectively protecting the test operator during the whole test process and avoiding the test operator from being infected by the virus. At the same time, the samples processed by the Sample preservation fluid Reagent containing protectene and all subsequent testing residual waste can effectively block the spread of the virus, avoid the pollution of medical waste, and facilitate the simple disposal of waste materials.

【The Main Components】

Kit components can be found in the table below:

Serial Number	Label	Ingredient	16 tests / box	24 tests / box	48 tests / box)	96 test / box
1	Sample preservation fluid	Hanks liquid, calf serum, antibiotics, protectene	16	24	48	96
2	Enzyme freeze-dried powder	Taq DNA enzyme, reverse transcriptase, SARS-CoV-2 primer probe	16 single tubes	24 single tubes	48 single tubes	96 single tubes
3	SARS-CoV-2 reaction fluid	Contains nucleotides of triphosphate, magnesium ions, purified water, etc.	1tube (450μL)	1tube (700μL)	1tube(1400μL)	2tube(1400μL)
4	SARS-CoV-2 Positive control (Optional)	TE solution containing the target gene	1 tube	1 tube	1 tube	1 tube
5	Instructions for use		1	1	1	1

Accessories required: Pipette, Pipette Tips, Vortex Mixer, and mini centrifuge

【Storage Conditions and Expiration Date】

The kit should be kept away from light and sealed at 2-8℃. Valid for 12 months.

Transport with foam box sealed with dry ice or ice pack.

Date of production and duration of use: see label.

【Applicable Instruments】

This kit is suitable for Anitoa Systems Maverick™ series fluorescent real time qPCR instruments.

【Sample Requirements】

1 The sample was taken from an unexplained patient of viral pneumonia or a suspected patient.

2 Sample types: pharynx swabs and nasal swabs;
3 Swallow swabs and preservation fluid need to be used in conjunction with.
If you do not use the sample preservation fluid provided with this test kit to deal with the collected sample, the sample should be dealt with as Nucleic acid extraction before PCR test, otherwise, the testing will not produce the correct results.
4 Sample storage conditions: Collected specimens should be sent for test in a timely manner, within 24 hours.

【The Test Method】

1 Sample processing
When using a kit or recommending sample preservation fluid, no additional sample extraction is required.
2 Reagent addition (sample treatment area).
Based on 25μL/reaction, the"SARS-CoV-2 reaction fluid" is added to a PCR tube containing freeze-dried reagents. Place in a vortex mixer for 30 seconds， and the above sample preservation fluid is added 10μL/ reaction, capped, placed in a vortex mixer for 30 seconds, and instantly centrifuged, transferred to PCR amplification zone.
3 Detection (PCR amplification zone).
Place the PCR reaction tube in the Anitoa labs MQ/Z/F series fluorescent PCR instrument and set the cycle parameters as follows:

Steps	The number of cycles	The temperature	Reaction time (min:sec).
1	1	50	08:00
2	1	95	01:00
3	40-45	95	00:02
		58	00:08

Fluorescent signals are collected as FAM(RdRp-N gene), VIC(internal control), ROX(Delta), and CY5(Omicron). The data is collected at 58℃.

【Explanation of The Test Results】

After the reaction, the instrument automatically saves the results

1 Result determination

Select each fluorescent channel to read the Ct value, and determine against the following table:

Ct value	Fam		
	Ct≤38.5	38.5＜Ct≤39.0	Ct＞39.0 or no Ct
The result is determined	RdRp/N gene positive	Suspected RdRp/N gene positive	RdRp/N negative

When the RdRp/N gene is positive, it can be judged to be positive for a novel coronavirus infection, otherwise it is negative for a novel coronavirus.

Ct value	Rox		
	Ct≤38.5 and the difference between the Ct of the FAM is less than 5	38.5＜Ct≤39.0 and the difference with the Ct of the FAM is less than 5	Ct＞39.0 or no Ct
The result is determined	Covid-19&Delta positive	Suspected Covid-19&Delta positive	Covid-19&Delta negtive

When the delta gene is positive, it can be judged to be positive for a novel coronavirus delta infection, otherwise it is negative for a novel coronavirus.

Ct value	Cy5		
	Ct≤38.5 and the difference between the Ct of the FAM is less than 5	38.5＜Ct≤39.0 and the difference with the Ct of the FAM is less than 5	Ct＞39.0 or no Ct
The result is determined	Covid-19&Omicron positive	Suspected Covid-19&Omicron positive	Covid-19&Omicron negtive

When the omicron gene is positive, it can be judged to be positive for a novel coronavirus omicron infection, otherwise it is negative for a novel coronavirus.

2 Quality control:
In the same experiment, the following conditions need to be met at the same time, otherwise the PCR reaction is considered invalid and needs to be retested. Here's how:
2.1 The target gene for the Positive control should show a typical amplification curve, and the Ct value ≤30.0;
2.2 In general, the internal control gene of the detection should show a typical amplification curve, and the Ct value ≤38.0;

【Limitations of The Test Method】

1 The test results of this kit are for clinical reference only, and the clinical diagnosis and treatment of patients should be considered in conjunction with their symptoms/signs, medical history, other laboratory examinations and treatment responses.
2 Sample test results are related to the quality of sample collection, processing, transport and preservation, and any errors will result in false negative results.
3 False positive results may occur if cross contamination is not controlled during sample processing.
4 For kits with inclusions, failure to amplify the inner label can result when the sample concentration is too high.

【Product Performance Indicators】

20 repeated test simulation samples showing the minimum detection limit for this product: 1000copies/ml sensitivity, CV<5%.
Comparative tests from clinical samples showed a positive compliance rate of 100% and a negative compliance rate of 100%.

【Note】

1. The whole testing process should be divided into three areas, one area for reagent preparation, two areas for specimen treatment, reaction system formulation, three areas for amplification, fluorescence detection and results analysis. Instruments, equipment, and work clothes are used independently in each district to prevent contamination.
2. In operation, should always take care to avoid RNase and DNase pollution, should use non-fluorescent substances disposable gloves (often replaced), disposable thin-walled 200 uL PCR tube (or 96-hole PCR plate plus optical film), pipette head (with filter dump), cannot touch the reaction tube directly by hand.
3. The treatment of specimens should use biosecurity cabinets to ensure operator safety and prevent environmental pollution. Harmful and toxic specimens and reagents in the experiment should be properly placed and kept by special persons; Instruments such as operator stations, pipettes, centrifuges, amplifiers, etc. should often be wiped and disinfected with 1.0% sodium hypochlorite and/or 70% ethanol. Experiment room, ultra-clean workbench should be regularly and after each experiment with UV lamp treatment.
4. Centrifugal tube reagents should be fully melted before use, mixed, centrifugal for a few seconds, so that the liquid concentrated in the bottom of the centrifugal tube. When formulating the reaction system should pay attention to: all liquid mixing as far as possible on the vortex mixer, do not use pipette blowing, do not produce bubbles, reaction system formulation finished low-speed centrifugal for a few seconds. Kits should be used during the shelf life. Reagents with different batch numbers should not be mixed.
5. Partition detection is not required when using the Glray Gene Q Series fully automatic fluorescent PCR instrument. Pay attention to the timely cleaning of medical waste.

【Reference】

[1] Victor Corman, Tobias Bleicker, Sebastian Brunink ,et al. Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR；Berlin, Protocol and preliminary evaluation.13.01.2020.
[2] Hui DS, I Azhar E, Madani TA, et al. The continuing 2019-nCoV epidemic threat of novel coronaviruses to global health - The latest 2019 novel coronavirus outbreak in Wuhan, China. Int J Infect Dis. 2020 Jan 14;91:264-266.

【Basic Information】

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Description of Symbols

Symbol	Descriptions	Symbol	Descriptions
LOT	**Batch Code**		**Date of Manufacture**
	Consult Instructions For Use	IVD	**In Vitro Diagnostic Medical Device**
	Keep Dry	EC REP	**Authorized Representative in The European Community**
	Do Not Re-use		**Do Not Use If The Package Is Damaged**
	Temperature limit	Σ	**Contains Sufficient for <n> Tests**
	Use-by Date	CE	**CE Mark**

	**Manufacturer**		