FOSUN PHARMA 复星医药
DIAGNOSTICS 医学诊断

NOVEL CORONAVIRUS (2019-NCOV) RT-PCR DETECTION KIT

Features

Comprehensive 3 targets (ORF1ab, N and E genes) detected in 1 tube

Reliable Internal control, UNG enzyme and dUTP were used to reduce risk of contamination and false negative results

Faster results 1.5 hours post-extraction turnaround time

Sample Type Nasopharyngeal swab/ Throat swab / Sputum/Stool

Instrument Four-channel RT-PCR instrument (FAM/JOE/ROX/CY5)

Product information

Registration certificate	CE: Ref. No.: GZ 8821-2020 China NMPA: GUOXIEZHUZHUN 20203400299
Specification	48 tests/kit; 96 tests/kit
Sample type	Nasopharyngeal swab/ Throat swab / Sputum/Stool
Sensitivity	300 copies/mL
Amplification time	1h20min
Instrument	Four-channel RT-PCR instrument(FAM/JOE/ROX/CY5)
Storage & Shelf Life	-25℃~-15℃, 12 months

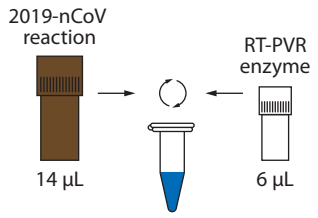
Performance

	Clinical Diagnostic Results		Total
	Positive	Negative	
Positive	209	8	217
Negative	1	376	377
Total	210	384	594

Compared with the results of clinical diagnosis, the clinical sensitivity was 99.53%, and the clinical specificity was 97.92%.

Workflow

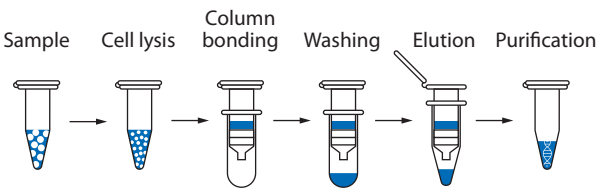
1



Step 1: Reagent preparation

Add n × 6 μL of RT-PCR enzyme and n × 14 μL of 2019-nCOV reaction reagent into the centrifuge tube, mix by shaking, and centrifugate at low speed for a few seconds, then make aliquots of 20 μL into different PCR reaction tubes.

2



Step 2: Nucleic Acid Extraction

The volume of sample to be extracted is 200 μL, and 5 μl of internal reference A will be added to each sample (including the reference);

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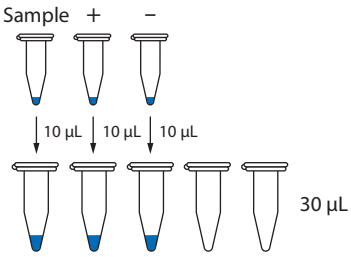

Step 3: Template Addition

Add 10 μL of extracted Negative Control, 10 μL of extracted Positive Control, and 10 μL of extracted RNA from sample to different PCR reaction tubes. Centrifuge them at low speed. Then, move them to the Real-time PCR instrument.

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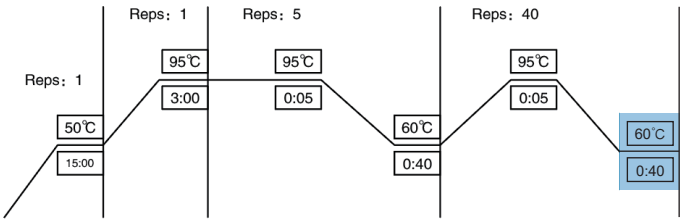

Step 4: PCR Amplification

1. 50℃ for 15 minutes, 1 cycle;
2. 95℃ for 3 minutes, 1 cycle;
3. 95℃ for 5 seconds to 60℃ for 40 seconds, 5 cycles;
4. 95℃ for 5 seconds to 60℃ for 40 seconds, 40 cycles. The signals of FAM, JOE, ROX and CY5 fluorescence channels will be collected at 60℃

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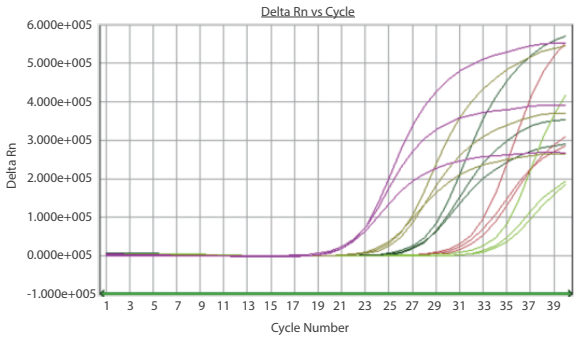

Step 5: Data Analysis

Test data file need to be saved after PCR reaction. Please set the parameters and analysis the results of FAM, JOE, ROX and CY5 channels respectively.

Note:

The nucleic acid extraction reagent used in Step 2 is not provided in the kit, which needs to be prepared by the user.

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