深圳市尚维高科有限公司
Shenzhen Shineway Technology Corporation

COVID-19 Nucleic Acid Detection Kit
(SW-nCoV-01)

Product Performance Report

Shenzhen Shineway Technology Corporation
Room 1206, Block 18B, ZhongHaiXin City of Innovative Industry,
Gan Li 2nd Road No.11 Jihua Street, Longgang District, Shenzhen,
Guangdong Province,China,518116
Fax：0755-89587395 Telephone:0755-89587395

EC REP N/A

E - mail：shineway@swtech.me Website：http：//www. soengwai.com

1. Product overview

1.1 Product introduction

1.1.1 COVID-19 Nucleic Acid Detection Kit (SW-nCoV-01)

The RT-PCR detection reagent for the new coronavirus is designed based on the ORF1ab and N gene regions provided in the "Technical Guide for the Detection of Novel Coronavirus Infected Pneumonia." It employ TaqMan fluorophores probe as the fluorescence signal acquisition, containing RNA virus detection enzyme and Buffer system. The kit uses PCR method with fluorescent probe amplification technology that could quickly detect the new type of coronavirus (COVID-19) RNA in the sample. The reaction is performed continuously in the same tube, which is simple to operate and can effectively prevent contamination.

Figure1 Product appearance（SW-nCoV-01）

1.2 Specification, model and life time

1.2.1 COVID-19 Nucleic Acid Detection Kit (SW-nCoV-01)

Technical Index	Parameters
Sensitivity	1000 copies / ml
CV Between Batches	⩽3%
CV Within Batch	⩽2%

Specificity	100%
Contents	Nucleic acid amplification reaction solution, COVID-19 reaction solution, RT-PCR enzyme mix, Positive reference, Sterile water and etc.
Sample	Throat swabs, nasal swabs, nasopharyngeal or respiratory extracts, deep cough sputum, bronchial lavage fluid, alveolar lavage fluid, blood specimens, serum specimens, fecal specimens, and conjunctival swab Specimens, etc.
Fluorescence Signal	FAM

COVID-19 Nucleic Acid Detection Kit (SW-nCoV-01) does not adversely affect the health or the safety of the patients, the user and other persons within the lifetime of the product.

2.5 Sensitivity of COVID-19 nucleic acid detection kit

1. Materials and Instruments

1.1 Materials

COVID-19 Nucleic Acid Detection Kit (batch number 20200120) from Shenzhen Shineway Technology Corporation

1.2 Instruments

1 ml, 200 μl, and 10 μl pipette tips, 1.5 ml EP tube, Axygen PCR tube; equipment: Eppendorf pipette, Bioer real-time PCR detection system FQD-48A

2. Method

2.1 Reaction Solution Preparation

25 μl system: 5 μl template + 20 μl reaction solution;Use water as template for blank control. Positive reference (10 ng/μl) is a synthetic plasmid template, which is diluted by 10 times. We could get 8 plasmid solutions of 1 ng/ μL, 0.1 ng/ μL, 0.01 ng/ μL, 1 pg/ μL, 0.1 pg/μL, 0.01 pg/ μL, 1 fg/ μL and 0.1 fg/μL, respectively.

Template	5 μl
RT-PCR buffer	16 μl
COVID-19 reaction solution -（N & ORF）	2 μl
RT-PCR enzyme	2 μl

2.2Amplification reaction procedure

	Reverse transcription	50 ℃，15 min
	Initial denaturation	95 ℃，3 min
	Denaturation	95 ℃，10 s
	Annealing+ Extension	55℃，40 s

3. Result

3.1 N gene

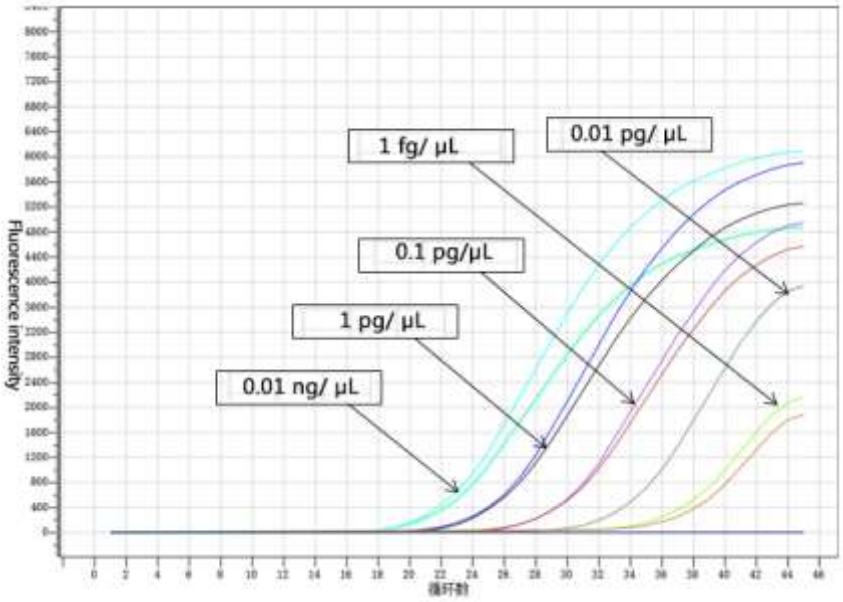

Figure 2 Amplification curve of COVID-19 (N gene)

The detection sensitivity of the kit for N gene was about 10^{-6} ng / μl (about 40 copies / μl), and the CT value was about 36.6.

3.2 ORF gene

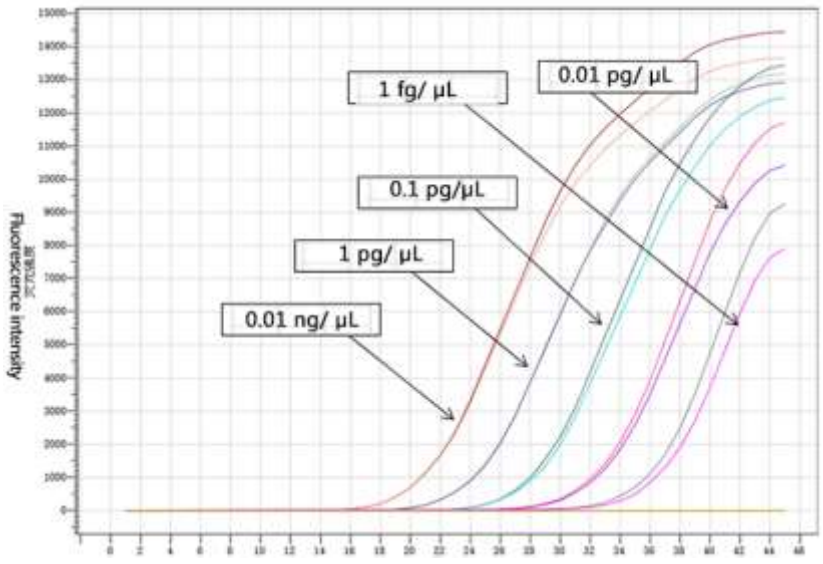

Figure 3 Amplification curve of COVID-19 (ORF gene)

The detection sensitivity of the kit for ORF gene was about 10^{-6} ng / μl (about 40 copies / μl), and the CT value was about 35.96.

4. Conclusion

The detection sensitivity of primer probes (N and ORF) were both 10^{-6} ng / μl (about 40 copies / μl), which achieved high detection rate for new coronaviruses.

2.6 Specificity of COVID-19 nucleic acid detection kit

The kit for nucleic acid detection of COVID-19 were designed based on COVID-19 specific sequences. The primer probe sequences compares to NCBI and the designed sequences do not cross with other coronaviruses such as SARS and MERS. Other common respiratory viruses such as influenza A virus, influenza B virus, syncytial virus, rubella virus, and metapneumovirus do not interfere with specific test for COVID-19. It was verified that the specificity of the COVID-19 primer probe was consistent with the comparison result, and only the novel coronavirus nucleic acid could be specifically detected.

1. Materials and Instruments

1.1 Materials

1.1.1 COVID-19 Nucleic Acid Detection Kit (batch number 20200120) from Shenzhen Shineway Technology Corporation;

1.1.2 The genomic nucleic acids of influenza A virus, influenza B virus, syncytial virus, rubella virus, metapneumovirus, and COVID-19 are provided by the cooperative institutes.

1.2 Instruments

1 ml, 200 μl, and 10 μl pipette tips, 1.5 ml EP tube, Axygen PCR tube; equipment: Eppendorf pipette, Roche 480 real-time PCR machine

2. Method

2.1 Reaction Solution Preparation

25 μl system: 5 μl template + 20 μl reaction solution; Use water as template for blank control. 4 parallel experiments.

Table 1

Template	5 μl
RT-PCR buffer	16 μl
nCoV reaction solution -N（or ORF）	2 μl
RT-PCR enzyme	2 μl

2.2Amplification reaction procedure

Table 2

	Reverse transcription	50 ℃，15 min
	Initial denaturation	95 ℃，3 min
	Denaturation	95 ℃，10 s
	Annealing+ Extension	55℃，40 s

3. Result

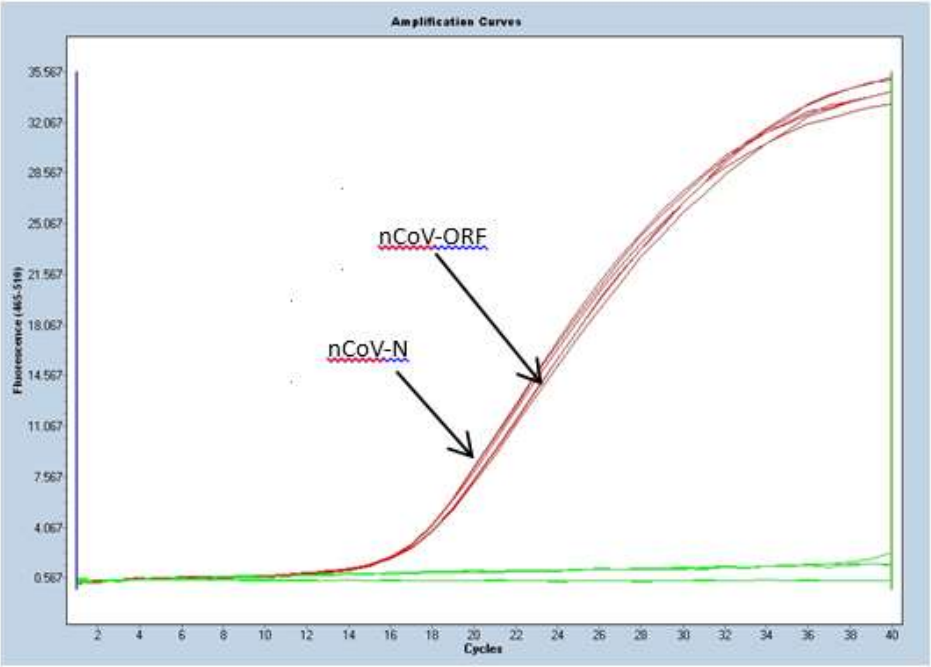

Figure 4 Specificity test for COVID-19 nucleic acid detection kit

It can be shown that nucleic acids of COVID-19 could be amplified specifically (red curve in the figure). The results of influenza A virus, influenza B virus, syncytial virus, rubella virus, and metapneumovirus were all negative (shown in the green curve) throughout the reaction. The experimental result indicated that the kit have strong specificity for the COVID-19.

4. Conclusion

The COVID-19 nucleic acid detection kit shows good sensitivity and specificity for novel coronavirus pneumonia, which is suitable for the detection of this epidemic.