



 **SEASUN**  
BIOMATERIALS

*We are showing vision about Future vision*

# **SEASUN BIOMATERIALS**

**SSf-COVID19**

(SARS-CoV-2 Real-time PCR Detection Kit)

[www.seasunbio.com](http://www.seasunbio.com)

# SSf-COVID19

- **SSf-COVID19** is a Real-Time PCR based *in vitro diagnostic* product intended for [detection of the New coronavirus SARS-CoV-2 \(RdRp, E\) RNA](#) in bronchoalveolar lavage, oropharyngeal or nasopharyngeal smears collected from patients with suspect viral infection.



100 rxn/box

## Feature

**Hot Start PCR** : High Specificity, No cross reaction

**One Step Multiplex PCR** : Multi-target analysis in a single reaction

**Probe method** : High specificity and minimal false positive rate

**IC** : Using the Human RNase P-No false negative

## Specification

Detection Target	RdRp gene, E gene
Composition of Tube	Single Tube / test
Detection Probe	TaqMan probe
Internal control	Human RNase P (endogenous control)
Sensitivity (Limit of Detection)	1 copy/ul
Run time	40 min
Analysis Program	COVID-19 Analyzer RV Panel Analysis : Korean, English, Spanish, Chinese)
Applicable specimens	RNA (with oropharyngeal and nasopharyngeal swab specimens)
Shelf life	Unopened 1 year / in-use 3 month

# SSf-COVID19

## 96well Plating & Amplification

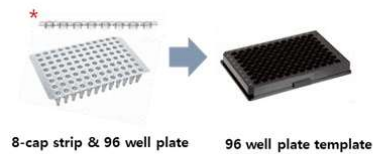
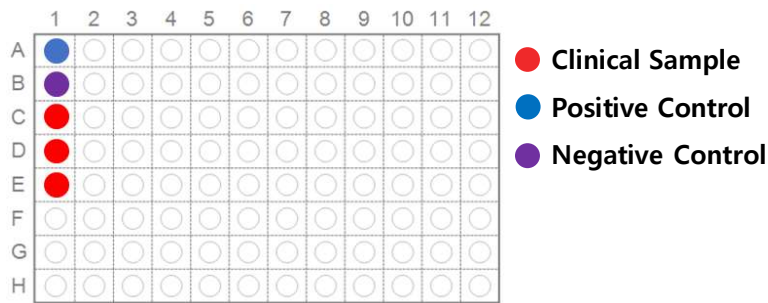
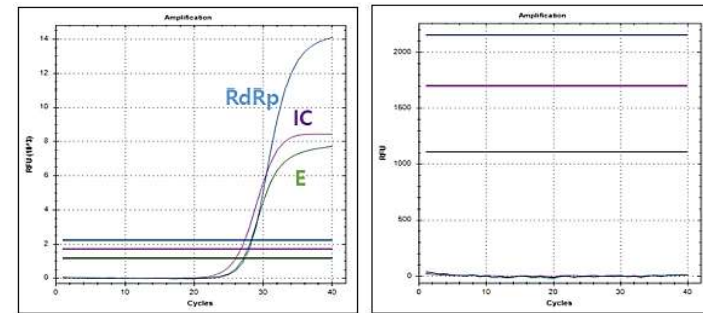


Plate Mixture setting



## Result Ct value



Positive

Negative

Control	SARS-CoV-2		IC
	FAM	HEX	Cy5
Negative	ND	ND	ND
Positive	≤38	≤38	≤38

- Positive and Negative control in 96-well plate are irrelevant (No fixed position)

# SSf-COVID19

## Reaction mixture

Reagent	Volume(ul)
2X Reaction Buffer	10
Reaction Mix	5
Template RNA	5
<b>Total</b>	<b>20</b>

## Target / Detection Channel

	Target gene	Detection channel
Detection	RdRp gene	FAM
	E gene	HEX
	RNase P	Cy5

## Run Information

Step	Temperature	Time	Cycle
cDNA synthesis	50°C	5 min	1
	95°C	1 min	1
Pre amplification	95°C	1sec	5
	62°C	15 sec	
Amplification	95°C	10 sec	40
	62°C	5 sec* / 30 sec**	

\* CFX96 : After 5 seconds of reaction, a fluorescence detection process is performed.

\*\* ABI7500 / Quantstudio5 : After 30 seconds of reaction, a fluorescence detection process is performed.

# SSf-COVID19

## Performance

Clinical Performance Test	
Limit of Detection	1 copy/ul of SARS-CoV-2 RNA
Specificity (Cross-reactivity, interference )	Cross-reactivity : 0% ( <i>In-silico</i> Analysis, Influenza A and 33 others) Interference : 0% (Interfering substances affecting the results, antibiotics and 7 others)
Precision (Reproducibility, Repeatability)	Coefficient of variation (%CV) $\leq$ 5% (PCR runs, Instruments, Technicians and different Batches of the kit)
Stability	1 year for un-opened product, 3 months after the first open
Quality controls	Endogenous control : human <i>RNase P</i> (Monitoring RNA quality) External control : <i>Positive</i> and <i>Negative</i> control (Evaluating assay performance )

(See the product IFU for more details)

**Clinical Specificity and Precision 100%**

# Appendix

## COVID-19 Test Products



< AQ-TOP COVID-19 Series >



< U-TOP COVID-19 Series >



< COVID-19 Genotyping > < COVID-19 & Flu A/B >

### Rapid Diagnosis (AQ-TOP)

**World Class 1<sup>st</sup>**  
(FDA Test)

**Probe**  
**LAMP PCR**  
**Method**

### Detailed Diagnosis (U-TOP)

**World Class 4<sup>th</sup>**  
(FDA Test)

**4 gene**  
**analysis**

### Multiple Assays

**SARS-CoV-2**  
**Mutation**  
**analysis**

**SARS-CoV2**  
**&**  
**Influenza**  
**multiplex**

## COVID-19 Products line

Sampling	TOP Viral Collection Kit	MFDS_IVD 2 US-FDA_EUA
	TOP Inactivating Collection Kit (Inactivation method)	
RNA Extraction	TOP Viral DNA/RNA Extraction Kit	MFDS_IVD 1
	SC V Extraction Kit (Rapid Extraction Kit, ~ 5min)	
Virus Detection	AQ-TOP COVID-19 Rapid Detection Kit (1 gene)	MFDS_IVD 3 US-FDA_EUA
	AQ-TOP COVID-19 Rapid Detection Kit Plus (2 gene)	
	U-TOP COVID-19 Detection Kit (2 gene multiplex analysis products)	
	U-TOP COVID-19 Detection Kit (4 gene multiplex analysis products)	MFDS_IVD 3 US-FDA (under review)
	U-TOP SARS-CoV2 & Flu A/B (SARS-CoV-2, Influenza multiplex)	
	AQ-TOP SARS-CoV-2 & Flu A/B (SARS-CoV-2, Influenza multiplex)	
	SSf-COVID19 (Completion of export license certification) (Fast real-time PCR, ~ 40min)	
SSu-COVID19 Plus (simultaneous detection and mutation analysis products)		