

STANDARD M
nCoV **Real-Time Detection Kit**

SARS-like coronavirus (SARS-CoV-2) Real-Time RT-PCR Kit

STANDARD M nCoV | Introduction



- Cat No. : 11NCO10
- Storage : -15°C ~ -25 °C
- Expiration date : 12 month
- Rox : reference dye for ABI 7500

Kit Contents

	Contents	Volume	Test volume
1	2019-nCoV Reaction Solution	750ul/vial x 2	14ul
2	RTase Mix	630ul/vial x 1	6ul
3	2019-nCoV Positive control	600ul/vial x 1	10ul
4	Negative control	600ul/vial x 1	10ul
5	Internal control A	525ul/vial x 1	5ul (Add with specimen) 0.5ul (amplification directly)
6	ROX	55ul/vial x 1	0.5ul
7	Instructions for use	1	

Target gene	Primer/probe	Sequence	Note
ORF1ab (RdRp) gene	ORF1 gene-forward primer	GTGARATGGTCATGTGTGGCGG	RdRp_SARSr-F2 (Germany)
	ORF1 gene-revers primer	CARATGTTAAASACACTATTAGCATA	RdRp_SARSr-R1 (Germany)
	ORF1 gene-probe (FAM)	CAGGTGGAACCTCATCAGGAGATGC	RdRp_SARSr-P2 (Germany)
E gene	E gene-forward primer	ACAGGTACGTTAATAGTTAATAGCGT	E_Sabeco-F1 (Germany)
	E gene-reverse primer	ATATTGCAGCAGTACGCACACA	E_Sabeco-R2 (Germany)
	E gene-probe (JOE)	ACACTAGCCATCCTTACTGCGCTTCG	E_Sabeco-P1 (Germany)

- **Multiplex PCR : Test two genes in one tube at simultaneously by diversifying probe fluorescence dye**
- *** IPC provided : Internal positive control for purification and amplification**

STANDARD M nCoV

Available instruments

- Can be used in variety instruments



AB 7500
Applied Biosystems



LC480 II
Roche



CFX 96
Bio-rad



SLAN
Shanghai Hongshi
Medical Technology

STANDARD M nCoV Real-Time Detection kit

Other detection kits

STANDARD M nCoV | Interpretation

Open the experiment data with the analysis software and perform the Ct analysis according to the instrument manual. See the table below for the Ct cut-off for each fluorescent channel.

Channel	Ct Value	Result
ORF1ab (RdRp) gene (FAM)	$Ct \leq 36$	2019-nCoV ORF1ab(RdRp) gene positive
E gene (JOE/VIX/HEX)	$Ct \leq 36$	2019-nCoV E gene positive
Internal Control (CY5)	$Ct \leq 32$	Internal control positive

Refer to the table below for the validity and the interpretation of each specimen result according to the results of each channel.

ORF1ab (FAM)	E gene (JOE)	IC (Cy5)	Interpretation
Positive	Positive	Positive	2019-nCoV positive
Positive	Negative	Positive	2019-nCoV positive
Negative	Positive	Positive	Near-source Coronavirus positive
Negative	Negative	Positive	2019-nCoV negative
Negative	Negative	Negative	Invalid / Re-test

- In case FAM/JOE signal is strong, Cy5(IC) could be undermined. If the retest is still the same, interpret the result except for the Cy5(IC) result.

STANDARD M nCoV

Analytical Performance

- Limit of Detection : 5×10^2 copies/mL (5 copies/reaction)

Concentration(copies/mL)	ORF1ab gene	E gene
5×10^3 copies/ml	100%(20/20)	100%(20/20)
1×10^3 copies/ml	100%(20/20)	100%(20/20)
5×10^2 copies/ml	95%(19/20)	100%(20/20)
1×10^2 copies/ml	45%(9/20)	50%(10/20)

- There is no cross reaction with 21 viruses or bacteria

No.	Category	Cross-reactivity substance	ID	ORF 1ab gene	E gene	Result
1	Non 2019-nCoV coronavirus infections	MERSr-CoV	1	No Ct	No Ct	negative
		HCoV-229E	2	No Ct	No Ct	negative
		HCoV-HKU1	3	No Ct	No Ct	negative
		HCoV-NL63	4	No Ct	No Ct	negative
		HCoV-OC43	5	No Ct	No Ct	negative
2	Non 2019-nCoV Viral infections	Influenza A virus	6	No Ct	No Ct	negative
		Influenza B virus	7	No Ct	No Ct	negative
		Respiratory syncytial virus	8	No Ct	No Ct	negative
		Rhinovirus	9	No Ct	No Ct	negative
		Parainfluenza virus	10	No Ct	No Ct	negative
3	Bacteria	Adenovirus	11	No Ct	No Ct	negative
		<i>Legionella pneumophila</i>	12	No Ct	No Ct	negative
		<i>Chlamydia pneumoniae</i>	13	No Ct	No Ct	negative
		<i>Mycoplasma pneumoniae</i>	14	No Ct	No Ct	negative
		<i>Haemophilus influenzae</i>	15	No Ct	No Ct	negative
		<i>Moraxella catarrhalis</i>	16	No Ct	No Ct	negative
		<i>Streptococcus pyogenes</i>	17	No Ct	No Ct	negative
		<i>Bowman Animal bacterium</i>	18	No Ct	No Ct	negative
		<i>Klebsiella pneumoniae</i>	19	No Ct	No Ct	negative
		<i>Pseudomonas aeruginosa</i>	20	No Ct	No Ct	negative
		<i>Streptococcus pneumonia</i>	21	No Ct	No Ct	negative

STANDARD M nCoV | Advantages

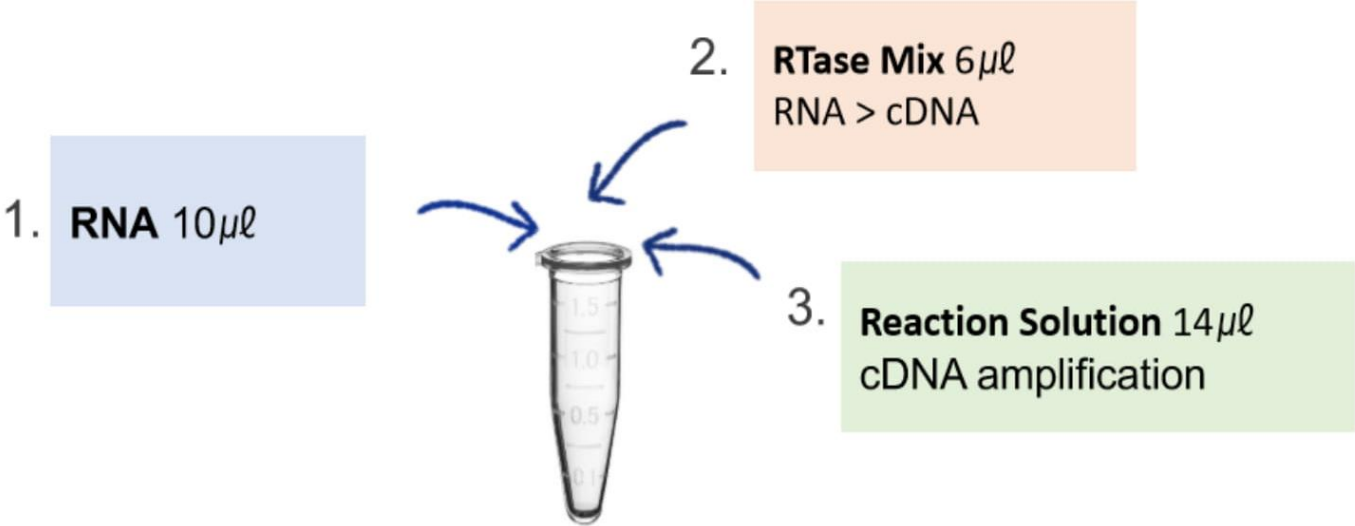
Fast 1-Tube Reaction | Specimen processing capacity x 2 ! hands-on time ↓ , Error ↓

	1 Tube Reaction STANDARD M nCoV Real-Time Detection kit	2 Tube Reaction Others
Protocol	[Easy to use]  RT-PCR Mix (RdRp/E gene) + RNA	 RT-PCR Mix (RdRp gene) + RNA  RT-PCR Mix (E gene) + RNA
Result Interpretation	[Clear Interpretation] - IC (Internal control) Valid – Interpret - IC Invalid – Retest	1 tube IC Valid / 2 tube IC Valid – Interpret 1 tube IC Invalid / 2 tube IC Valid – Retest 1 tube IC Valid / 2 tube IC Invalid – Retest 1 tube IC Invalid / 2 tube IC Invalid – Retest
Hands-on time	[Minimize User error] RT-PCR Mix 1 / Nucleic acid Adding 1	1 tube: RT-PCR Mix 1 / Nucleic acid adding 1 2 tube: RT-PCR Mix 1 / Nucleic acid adding 1 Hands-on Time X 2 / Error probability X2
Test capacity/experiment (1 instrument, 1 PC/run, 1 NC)	94T [Twice capacity more than others]	46T
Test capacity/day (5 experiments)	470 Tests	230 Tests

Winc
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STANDARD M nCoV | Advantages

Simple 1-Step Reaction | RT (Reverse transcription) process at once



Reaction	Temperature(°C)	Time	Cycle
Reverse transcription	50°C	15 mins	1
Initial denaturation	95°C	3 mins	1
Pre-amplification	95°C	5 secs	5
	60°C	40 secs	
Amplification	95°C	5 secs	40
	60°C	40 secs	
	Detection(FAM/JOE/Cy5)		

Win
[석정]

JOE (VIC or HEX)



THANK YOU

Contact : 1203 ho, 93, Sejong-daero, Jung-gu, Seoul, Republic of Korea
+82-10-9889-5445
kireisanohajime@gmail.com

