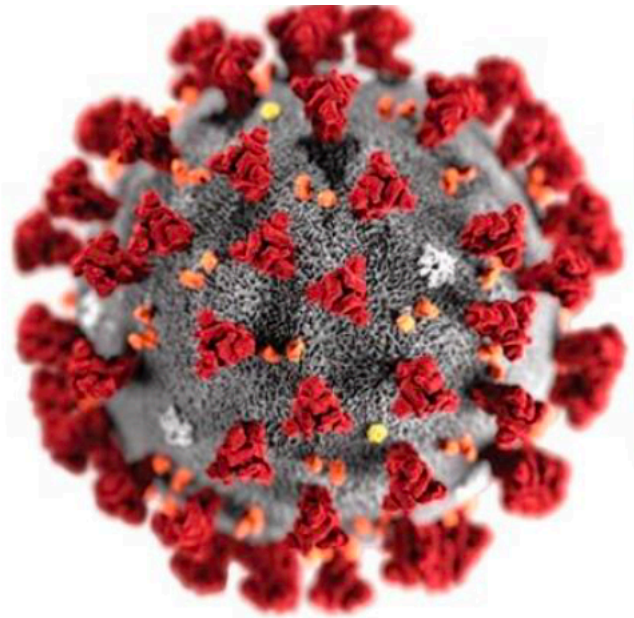


TOTAL SOLUTIONS FOR COVID-19 TESTING

DIAGNOSTIC TEST & PPE



SARS-CoV-2

STANDARD™ M nCoV Real-Time Detection kit

2019 New Coronavirus (COVID-19)

STANDARD M nCoV Real-Time Detection kit is used for rapid identification and detection of novel coronavirus (2019-nCoV) nucleic acids in human nasopharyngeal swabs and throat swab samples. Coronavirus RNA was first transcribed into cDNA by reverse transcriptase, and then cDNA was used as a template for PCR amplification. The separation of the fluorophore and quencher makes the fluorescence signal detected by the instrument: FAM channel qualitative detection of the new coronavirus (COVID-19) ORF1ab (RdRp) gene, and JOE (VIC or HEX) channel qualitative detection of coronavirus) E gene, and CY5 channel detection internal reference.

➤ Applications

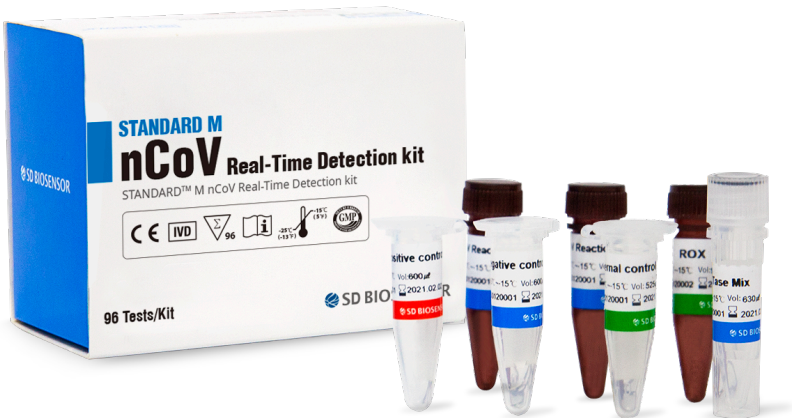
- Nasopharyngeal swab
 - Sputum
- Oropharyngeal swab

➤ Compatibility

- LightCycler 480 (Roche)
 - CFX96™ Dx System (Bio-Rad)
- Applied Biosystems 7500 Real-Time PCR Instrument System (Thermo Fisher Scientific)

➤ Benefits

Fast & Easy	High Sensitivity & Specificity
<ul style="list-style-type: none">• One tube reaction for identification and detection of 2019-nCoV• One-step Real-Time RT-PCR• Provide all reagents required for PCR	<ul style="list-style-type: none">• Designed according to “WHO interim guidance for laboratory testing for 2019 novel coronavirus (2019-nCoV) in humans”• nCoV primers/probes ORF1ab (RdRp) gene, E gene• Provide Internal controls



THE ONLY TEST IN THE MARKET WITH:
100% CLINICAL SENSITIVITY
100% CLINICAL SPECIFICITY

➤ **Benefits**

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➤ **Key Components**

	Components	Quantity	Test Dosage in each reaction
1	2019-nCoV Reaction Solution	750µl / vial x 2	14µl
2	RTase Mix	630µl / vial x 1	6µl
3	2019-nCoV Positive control	600µl / vial x 1	-
4	Negative control	600µl / vial x 1	-
5	Internal control A	525µl / vial x 1	5µl (Add with specimen) 0.5µl (Amplification directly)
6	ROX	55µl / vial x 1	0.5µl (for Applied Biosystems 7500)

➤ **Cycle Condition**

Reaction	Temperature (°C)	Running time	Cycle
Reverse transcription	50°C	15 minutes	1
Initial denaturation	95°C	3 minutes	1
Pre-amplification	95°C	5 seconds	5
	60°C	40 seconds	
Amplification	95°C	5 seconds	40
	60°C	40 seconds	
	Collect the signals of FAM, JOE* and CY5 fluorescence channels		



* FAM (ORF1ab (RdRp) gene), JOE*/VIC/HEX (E gene), Cy5 (IC)

➤➤ **FDA EUA Approved**

➤➤ **Korea EUA Approved**



CE

STANDARD M
nCoV Real-Time Detection kit

- Korea EUA Approved
- One tube reaction for identification and detection of 2019-nCoV
- One-step Real-Time RT-PCR
- Provide all reagents required for PCR

Advantages of STANDARD M nCoV

- ✓ Designed according to **WHO / KCDC** recommendations
- ✓ Easy to use **1 Tube** reaction
- ✓ Separately configured **Internal Control (IC)** to verify the whole process
- ✓ **Simple interpretation of results** (2 Target (RdRp / E gene) + 1 IC
- ✓ Outstanding analytical sensitivity **5 copies/reaction**
- ✓ A wide range of instrument compatibility **CFX96 / AB7500 / LC480**
- ✓ **Fast TAT** - **Within 90 minutes** after extraction
- ✓ **12 months of stability**
- ✓ **CE-IVD, KEUA** (Korean Emergency Use Authorization)

Contents



	Contents (96T/kit)	Quantity
1	2019-nCoV Reaction Solution	750µℓ/vial x 2
2	RTase Mix	630µℓ/vial x 1
3	2019-nCoV Positive control	600µℓ/vial x 1
4	Negative control	600µℓ/vial x 1
5	Internal control A	525µℓ/vial x 1
6	ROX*	55µℓ/vial x 1
7	Instructions for Use	1

- Cat. no.: 11NCO10
- 96 Tests/Kit
- Storage: -15°C ~ -25°C
- Stability: 12 months
- ROX: Reference dye (ABI 7500)

Items supplied with in testing kit:

2 vials x 2019-nCoV Reaction Solution (750μL)
1 vial x RTase Mix (630μL)
1 vial x 2019-nCoV Positive control (600μL)
1 vial x Negative control (600μL)
1 vial x Internal control A (525μL)
1 vial x ROX (55μL)
1x IFU

Items required, but not supplied in testing kit:

Nasal Swabs
Micropipette and tip
Blood Collection tube
PPE (Personal Protective Equipment)
Biohazard container
Viral RNA extraction kit
PCR reaction tube
Vortex mixer
Centrifuge