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Certificate of Analysis

Product Name	STANDARD M nCoV Real-Time Detection kit			
Ref No.	M-NCOV-01	Cat No.	11NCO10	
Lot No.	MNCO0120005	MFG Date	2020.03.12.	
		EXP Date	2021.03.11.	
Testing categories	Specification		Result	
Performance Inspection	Sensitivity: Over 95% detected in positive control diluted 100 times			Pass
	• Repeatability: Positive control and Internal control A values are within 24 ± 2 Ct			Pass
	Specificity: No fluorescence signal detected in negative control			Pass
Packaging Inspection	• Componets: 2019-nCoV Reaction Solution(750 $\mu\ell$ /vial) x 2 / RTase Mix(630 $\mu\ell$ /vial) x 1 / 2019-nCoV Positive control(600 $\mu\ell$ /vial) x 1 / Negative control(600 $\mu\ell$ /vial) x 1 / Internal control A(525 $\mu\ell$ /vial) x 1 / ROX(55 $\mu\ell$ /vial) x 1 / Test kit insert x 1 • Tube capping: All tubes should be closed • Tube color: There should be 3 brown tubes and 4 transparent tubes			Pass
	Check the text number of the labeling material			Pass
	 Expiration date between vial label and package of test kit LOT No. between vial label and package of test kit 			Pass

According to SD Biosensor's quality assurance system, the above QC tests have been completed and passed the specification. We hereby approve this product release.

SD Biosensor, Inc

Geunkuk Song
Ouality Management Representative
OA Division

Geunkuk Song

Quality Management Representative

QA Division Issue date: 2020-03-19