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Certificate of Analysis

Product Name	STANDARD™ Q COVID-19 Ag/Ab Total test		
Cat No.	09COV60D	Ref No.	Q-NCOV-01T
Lot No.	QCO6020002A	MFG Date	2020.06.02.
		EXP Date	2021.06.01.
Testing categories	Specification		Result
Appearance Inspection	<ul style="list-style-type: none"> The membrane is well seated. The mark on the appearance of the device is correct. Buffer is a colorless liquid formulation All Desiccant color must be yellow. 		Pass
Sensitivity	In-house reference panels for the sensitivity test 1) All panels must be interpreted as positive.		Pass
Specificity	In-house reference panels for the specificity test 1) Combo : 95.74% (95% CI: 92.31%~ 97.94%) 2) Ag : 100% (95% CI: 97.58%~100%)		Pass
Migration test	The migration of the product should appear in the results window within 2 minutes and should reach the end of the results window within 6 minutes.		Pass
Background test	The background of the product should be light red or clean within the reading time.		Pass
Packaging Inspection	STANDARD™ Q COVID-19 IgM/IgG Combo Test: Test devices(25T)/ Buffer bottle (1ea) / Transparent film (1ea)/ Capillary tube 20ul (25ea) / Alcohol swab (25ea) / Safety lancet (25ea) / Insert (1ea)		Pass
	STANDARD™ Q COVID-19 Ag Test: Test devices(25T)/ Extraction buffer tube (25 ea) / Transparent film (1ea)/ Nozzle cap(25ea) / Sterile swab(25ea) / Insert (1ea)		
	Manufacturing and expiration date between the pouch, buffer and package of test kit		Pass
	LOT No. between the pouch,buffer 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
Quality Management Representative
QA Division

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