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F-QP-0026-0016-0007

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Certificate of Analysis

Product Name	STANDARD™ Q COVID-19 Ag Test			
Cat No.	09COV33D	Ref No.	Q-NCOV-01G	
Main Lot/Sub Lot	5864CD1AC / 2	MFG Date	2023-12-13	
	5604CDTAC72	EXP Date	2025-09-25	
Testing categories	Specification		Result	
Apperance Inspection	 The mark on the appearance of the device is correct. Verify that the positions of the colored C line and T line are within the appropriate range. (Color Line Position Check) Buffer is a colorless liquid formulation. All desiccant color must be yellow. 			Pass
*In-house Reference panel Inspection	The positive specimen should be positive and the negative specimen should be determined to be negative.			Pass
Migration speed 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 condition test	Background of product should be light red or clean within the reading time.			Pass
Packaging Inspection	Test device (25ea) / Extraction buffer (Gray/Plain) (25ea) / Nozzle cap (25ea) / Sterile swab (25ea) / Positive control swab (1ea) / Negative control (1ea) / IFU (1ea)			Pass
	Manufacturing and expiration date on the pouch and package of test kit.			Pass
	LOT No. on the pouch and package of test kit.			Pass

* In-house Reference panel test: This test replaces sensitivity and specificity tests.

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.



Ko Jongkwan Quality Management Representative QA Division

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