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F-QP-0026-0016-0055 Rev.00 (2023.10.16.)

Certificate of Analysis

Product Name	STANDARD™ F COVID-19 Ag FIA			
Cat No.	10COV31D	Ref No.	F-NCOV-01G	
Main Lot	6564CM1AC	MFG Date	2023.12.21.	
		EXP Date	2025.06.20.	
Testing categories	Specification		Result	
Appearance Inspection	 Uniform Gap between upper and lower device No scratch, stain and crack etc. No contamination There should be colored lines. Check device type Check buffer amount 			Pass
Barcode Check	The product name and 'apply sample' should be displayed on the screen.			Pass
Sensitivity	In-house reference panels for the sensitivity test 1) Test result must be interpreted as positive 95% agreement.			Pass
Specificity	In-house reference panels for the specificity test 1) Test result must be interpreted as negative 95% agreement.			Pass
Packaging Inspection	Test Device (25ea) / Sterile swab (25ea) / Extraction buffer (25ea) / Nozzle cap (25ea) / IFU (1ea)		Pass	
	No leackage in sealing part of pouch		Pass	
	No leackage in sealing part of buffer solution tube		Pass	
	Manufacturing and expiration date between the pouch and package of test kit.		Pass	
	LOT No. between the pouch 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.

Ko Jongkwan

Quality Management Representative QA Division

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