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Headoffice: C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

TEL : +82-31-300-0400 / FAX : +82-31-300-0499 http://www.sdbiosensor.com

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	<ul> <li>Uniform Gap between upper and lower device</li> <li>No scratch, stain and crack etc.</li> <li>No contamination</li> <li>There should be colored lines.</li> <li>Check device type</li> <li>Check buffer amount</li> </ul>			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.



Jongkwan Ko Quality Management Representative QA Division

Page 1 of 1