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Certificate of Analysis

Product Name	STANDARD™ F COVID/Flu Ag Combo FIA			
Cat No.	10COV71D	Ref No.	F-CVFL-01C	
LOT No.	6554192AC	MFG Date	2023.01.09.	
		EXP Date	2024.07.08.	
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. LOT No. between the pouch and package of test kit.			Pass Pass
	LOT 110. between the pouch and package of test kit.			r изз

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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