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Certificate of Analysis

Product Name	STANDARD™ F Influenza A/B FIA			
Cat No.	10INF20D	REF No.	FINF01G	
Lot No.	FIN102009141	MFG Date	2020.09.14.	
		EXP Date	2022.03.13.	
Testing categories	Specification		Result	
Apperance Inspection	 Uniform Gap between upper and lower device No scratch, stain and crack etc. No contamination 			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) All panels must be interpreted as negative.			Pass
Precision	1) Within-run precision: must be identified 100% agreement within-run test results 2) Between-run precision: must be identified 100% agreement between-run test results			Pass
Packaging Inspection	Strip Devices (25strips) / Sterile swab (25ea) / Extraction buffer (25ea) / Filter cap(25ea)/Fixed volume dropper 300µl(25ea)/Positive control swab(1ea)/Negative control swab(1ea)/ insert (1ea)			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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