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> > Rev.00 (2023.10.16.)

## **Certificate of Analysis**

Product Name	STANDARD™ F Influenza A/B FIA			
Cat No.	10INF20D	Ref No.	FINF01G	
Main Lot	6014BV1AC	MFG Date	2023.	11.29.
		EXP Date	2025.	05.28.
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>		only	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) 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
Packaging Inspection	Test Device (25ea) / Sterile swab (25ea) / Extraction buffer (25ea) / Nozzle cap (25ea) / Fixed volume dropper(300ul) (25ea) / Positive control swab (1ea) / Negative control swab (1ea) / 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.



Ko Jongkwan Quality Management Representative QA Division

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