F-QP-0026-0016-0055



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Rev.00 (2023.10.16.)

Certificate of Analysis

Product Name	STANDARD™ F S.pneumoniae Ag FIA			
Cat No.	10SPN10D	Ref No.	FPNE01G	
Main Lot	6024BL2AC	MFG Date	2023.11.20.	
		EXP Date	2025.05.19.	
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	26 1160	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) / Fixed volume pipette(100ul) (25ea) / Control extraction buffer (2ea) / 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.

SD Biosensor, Inc.

Ko Jongkwan

Quality Management Representative **QA Division**

Jongkwan Ko

Quality Management Representative

QA Division