

F-QP-0026-0016-0055

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 S.pneumoniae Ag FIA				
Cat No.	10SPN10D	Ref No.	FPNI	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 		oply	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.



Ko Jongkwan Quality Management Representative QA Division

Jongkwan Ko Quality Management Representative QA Division

Page 1 of 1