

Importer Address: Plot No.38, Sector-4, IMT Manesar, Gurgaon, Haryana 122050, India 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

C-BD100-17-SF00-010 Rev.01 (2023.09.05.)

Certificate of Analysis

Product Name	STANDARD™ F Legionella Ag FIA				
Cat No.	10LEG10D	Ref No.	FLGN	FLGN01G	
Main Lot	60448A1AC	MFG Date	2023.0	08.10.	
		EXP Date	2025.0	02.09.	
Testing categories	Specif	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. Quality Management Representative **QA Division** Jongkwan Ko Quality Management Representative

QA Division

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