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Headoffice: C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggido, 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 iFOB FIA				
Cat No.	10IFO10C	Ref No.	F-FO	F-FOB-01	
Main Lot	6364AR1AC	MFG Date	2023.	10.25.	
		EXP Date	2025.	04.24.	
Testing categories	Specification		Result		
Appearance Inspection	 Uniform Gap between upper and lower device No scratch, stain and crack etc. No contamination There should be no colored lines. Check device type Check buffer amount 			Pass	
Barcode Check	The product name and 'apply sample' should be displayed on the screen.			Pass	
Repeatability	• Feces $CV \le 10\%$			Pass	
Dynamic range	• Testing temperature range: 15-32°C 59-90°F • Testing Range: 50~800 ng/mL			Pass	
Packaging Inspection	50 Test Device, 50 Sample collection tube with assay diluent , 50 Sample collection tube bag, 50 Patient ID Label, 1 IFU		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.





Jongkwan Ko Quality Management Representative QA Division

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