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## **Certificate of Analysis**

Product Name	STANDARD™ F iFOB FIA			
Cat No.	10IFO10C	Ref No.	F-FOB-01	
Main Lot	6364AR1AC	MFG Date	2023.10.25.	
		EXP Date	2025.04.24.	
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 no colored lines.</li> <li>Check device type</li> <li>Check buffer amount</li> </ul>			Pass
Barcode Check	The product name and 'apply sample' should be displayed on the screen.			Pass
Repeatability	• Feces CV ≤ 10%			Pass
Dynamic range	• Testing temperature range: 15-32°C   59-90°F • Testing Range: 50~800 ng/mL			Pass
Packaging Inspection	$50\ \mathrm{Test}$ Device, $50\ \mathrm{Sample}$ collection tube with assay diluent , $50\ \mathrm{Sample}$ collection tube bag, $50\ \mathrm{Patient}$ ID Label, $1\ \mathrm{IFU}$			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.

SD Biosensor, Inc.

Ko Jongkwan

Quality Management Representative **QA** Division

Jongkwan Ko

**Quality Management Representative QA** Division