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Certificate of Analysis

Product Name	STANDARD™ F D-dimer FIA			
Cat No.	10DDI10B	Ref No.	F-DDI-01	
Main Lot	61649K1AC	MFG Date	2023.09.19.	
		EXP Date	2025.03.18.	
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	 Plasma CV ≤ 12.5% Whole blood CV≤ 17.5% 			Pass
Dynamic range	 Testing temperature range: 15-32°C 59-90°F Testing Range: 25 ~ 5000 ng/mL FEU 			Pass
Packaging Inspection	20 Test Device, 20 Buffer, STANDARD™ Ezi tube+ (10ul) (20ea), Disposable dropper 100μl(20ea), 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.

SD Biosensor, Inc.

Ko Jongkwan

Quality Management Representative **QA** Division

Jongkwan Ko

Quality Management Representative

QA Division