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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	<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	<ul> <li>Plasma CV ≤ 12.5%</li> <li>Whole blood CV≤ 17.5%</li> </ul>			Pass
Dynamic range	<ul> <li>Testing temperature range: 15-32°C   59-90°F</li> <li>Testing Range: 25 ~ 5000 ng/mL FEU</li> </ul>			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