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Certificate of Analysis

Product Name	STANDARD™ F TnI Pro FIA				
Cat No.	10HST20B Ref No. F-TN		F-TNI-02		
LOT No.	65145R1AC	MFG Date	2023.05.25.	2023.05.25.	
		EXP Date	2024.11.24.		
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. The tablet must not be damaged. Check device type Check buffer amount 			Pass	
Barcode Check	The product name and 'apply sample' should be displayed on the screen.			Pass	
Repeatability	• Serum, Whole blood CV ≤ 15%			Pass	
Dynamic range	 Testing temperature range: 15-32°C 59-90°F Testing Range: 10 ~ 20,000 ng/L 			Pass	
Packaging Inspection	20 Test Device, 20 Buffer, 20 Disposable dropper(100μl), 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 p	LOT No. between the pouch and package of test kit.			

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

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