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Certificate of Analysis

Product Name	STANDARD™ F PCT FIA			
Cat No.	10PCT20B	Ref No.	F-PCT-02	
LOT No.	6064533AC	MFG Date	2023.05.03.	
		EXP Date	2024.11.02.	
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	• Serum/ Plasma CV ≤ 10% • Whole blood CV≤ 15%			Pass
Dynamic range	Testing temperature range: 15-32°C 59-90°F Testing Range: 0.05-50 ng/mL			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 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.



Ko Jongkwan

Quality Management Representative QA Division

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Quality Management Representative

QA Division