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Certificate of Analysis

Product Name	STANDARD™ F hs-CRP			
Cat No.	10HSC10B	Ref No.	F-HCRP	
LOT No.	6184121AC	MFG Date	2023.01.02.	
		EXP Date	2024.07.01.	
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	• Whole blood, Serum, Plasma CV \leq 15%			Pass
Dynamic range	 Testing temperature range: 15-32°C 59-90°F Testing Range whole blood : 0.1-15.0 mg/L Serum/Plasma : 0.1-15.0 mg/L 			Pass
Packaging Inspection	20 Test Device, 20 Buffer, 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 I	backage 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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