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## **Certificate of Analysis**

Product Name	STANDARD™ F β-hCG FIA			
Cat No.	10BHC10B	Ref No.	F-HCG	
LOT No.	6214141AC	MFG Date	2023-01-04	
		EXP Date	2024-07-03	
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	• Serum $CV \le 10\%$ • Whole blood $CV \le 15\%$ Seas use on V			Pass
Dynamic range	<ul> <li>Testing temperature range: 15-32°C   59-90°F</li> <li>Testing Range: 5-1500 mIU/mL</li> </ul>			Pass
Packaging Inspection	20 Test Device, 20 Buffer, 20 Fixed volume pipette (50µl), 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.



Ko Jongkwan

Quality Management Representative QA Division

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