F-QP-0026-0016-0054



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http://www.sdbiosensor.com Rev.00 (2023.10.16.)

## **Certificate of Analysis**

Product Name	STANDARD™ F CRP			
Cat No.	10CRP10B	Ref No.	F-CRP	
Main Lot	6094BE6AC	MFG Date	2023.11.14.	
		EXP Date	2025.	05.13.
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>The tablet must not be damaged.</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	• Whole blood, Serum, Plasma CV $\leq 15\%$			Pass
Dynamic range	<ul> <li>Testing temperature range: 15-32°C   59-90°F</li> <li>Testing Range</li> <li>whole blood : 1.0-150 mg/L</li> <li>Serum/Plasma : 1.0-130 mg/L</li> </ul>			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 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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