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## **Certificate of Analysis**

Product Name	STANDARD™ F C.difficile Toxin A/B FIA			
Cat No.	10CDT10D	Ref No.	F-CDFT-01	
LOT No.	6083BW1AC	MFG Date	2022.11.30.	
		EXP Date	2024.05.29.	
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 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
Sensitivity	In-house reference panels for the sensitivity test 1) Test result must be interpreted as positive 95% agreement.			Pass
Specificity	In-house reference panels for the specificity test 1) Test result must be interpreted as negative 95% agreement.			Pass
Packaging Inspection	Test Device (25ea) / Sterile swab (25ea) / Extraction buffer (25ea) / Filter cap (25ea) / IFU (1ea)			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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