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F-QP-0026-0016-0097

Rev.00 (2023.10.16.)

## Certificate of Analysis

Product Name	STANDARD™ M10 C. difficile		
Cat No.	11CDC10A	Ref No.	M10-CDF-01
Lot No.	8CF73G1AJ1	MFG Date	2026-03-16
		EXP Date	2027-03-15
Testing categories	Specification		Result
Performance Inspection	• Sensitivity: 100% detected in 2X LoD		Pass
	• Repeatability: Results are within $\pm 2$ Ct of target concentration		Pass
	• Specificity: No fluorescence signal detected in negative control		Pass
Apperance Inspection	• Check the text number of the labeling material		Pass
	• Quantity per one container : 10ea		
	• Expiration date between cartridge label and package of test kit		Pass
	• LOT No. between cartridge label 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.**

**SD Biosensor, Inc.**

Ko Jongkwan

Quality Management Representative  
QA Division

Jongkwan Ko  
Quality Management Representative  
QA Division