



Headoffice: C-4th&5th, 16, Deogyong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

TEL : +82-31-300-0400 / FAX : +82-31-300-0499
<http://www.sdbiosensor.com>

Certificate of Analysis

Product Name	STANDARD™ F C.difficile GDH FIA		
Cat No.	10CDG10D	Ref No.	F-CDFG-01
LOT No.	64241J2AC	MFG Date	2023.01.18.
		EXP Date	2024.07.17.
Testing categories	Specification		Result
Appearance Inspection	<ul style="list-style-type: none"> • Uniform Gap between upper and lower device • No scratch, stain and crack etc. • No contamination • There should be colored lines. • Check device type • Check buffer amount 		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 leakage in sealing part of pouch		Pass
	No leakage 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.

SD Biosensor, Inc.

Ko Jongkwan 
 Quality Management Representative
 QA Division

Ko Jongkwan
 Quality Management Representative
 QA Division