

Importer Address: Plot No.38, Sector-4, IMT Manesar, Gurgaon, Haryana 122050, India Headoffice: C-4th&Sth, 16, Deogyeong-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

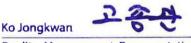
> TEL: +82-31-300-0400 / FAX: +82-31-300-0499 http://www.sdbiosensor.com

## **Certificate of Analysis**

Product Name	STANDARD™ F Dengue NS1 Ag FIA			
Cat No.	10DEN10D	Ref No.	FDEN01G	
LOT No.	64746K2AC	MFG Date	2023.06.19.	
		EXP Date	2024.12.18.	
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) All panels must be interpreted as positive.			Pass
Specificity	In-house reference panels for the specificity test 1) All panels must be interpreted as negative.			Pass
Packaging Inspection	Test Device (25ea) / Disposable dropper100µl (25ea) / Assay diluent buffer (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 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.





Quality Management Representative QA Division

Ko Jongkwan Quality Management Representative QA Division Issue date: 2023.07.18.