



Certificate of Analysis

Product Name	STANDARD™ F Dengue IgM/IgG FIA		
Cat No.	10DEN20D	Ref No.	FDEN01B
Main Lot/Sub Lot	64873S1AC / 1	MFG Date	2026-03-26
		EXP Date	2027-09-25
Testing categories	Specification		Result
Appearance Inspection	• 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) 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) / Ezi tube10μl (25ea) / Assay diluent buffer 4ml (1ea) / 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

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Quality Management Representative
QA Division