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Certificate of Analysis

Product Name	STANDARD™ F H.pylori Ag FIA			
Cat No.	10HPY10D	Ref No.	F-HPY-01	
LOT No.	62545P2AC	MFG Date	2023.05.23.	
		EXP Date	2024.11.22.	
Testing categories	Specification			Result
Appearance Inspection	 Uniform Gap between upper and lower device No scratch, stain and crack etc. No contamination There should be no 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) / Sterile swab (25ea) / Extraction Buffer Tube (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 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.



Ko Jongkwan

Quality Management Representative QA Division

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