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Certificate of Analysis

10HPY10D 62545P2AC	Ref No. MFG Date EXP Date	F-HPY-01 2023.05.23.		
62545P2AC				
62545P2AC	EXP Date		2023.05.23.	
		EXP Date 2024.11.22.		
Specification			Result	
 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		
The product name and 'apply sample' should be displayed on the screen.		Pass		
In-house reference panels for the sensitivity test 1) All panels must be interpreted as positive.		Pass		
In-house reference panels for the specificity test 1) All panels must be interpreted as negative.		Pass		
Test Device (25ea) / Sterile swab (25ea) / Extraction Buffer Tube (25ea) / Filter cap (25ea) / IFU (1ea)		e (25ea) /	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. LOT No. between the pouch and package of test kit.		Pass		
	panels must be interpreted a use reference panels for the s panels must be interpreted a Device (25ea) / Sterile swab (cap (25ea) / IFU (1ea) ackage in sealing part of pour ackage in sealing part of buff	panels must be interpreted as positive. use reference panels for the specificity test USE panels must be interpreted as negative. Device (25ea) / Sterile swab (25ea) / Extraction Buffer Tube cap (25ea) / IFU (1ea) ackage in sealing part of pouch ackage in sealing part of buffer solution tube	panels must be interpreted as positive. use reference panels for the specificity test USE ONY panels must be interpreted as negative. Device (25ea) / Sterile swab (25ea) / Extraction Buffer Tube (25ea) / cap (25ea) / IFU (1ea) ackage in sealing part of pouch ackage in sealing part of buffer solution tube	

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.





QA Division Ko Jongkwan

Quality Management Representative QA Division