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Certificate of Analysis

Product Name	STANDARD™ F RSV Ag FIA		
Cat No.	10RSV10D	Ref No.	FRSV01G
Main Lot	64645A2AC	MFG Date	2023.05.10.
		EXP Date	2023.11.09.

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) / Sterile swab (25ea) / Extraction buffer (25ea) / Nozzle cap (25ea) / Fixed volume dropper(300ul) (25ea) / Positive control swab (1ea) / Negative control swab (1ea) / 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*

For overseas use only

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 고종관
Quality Management Representative
QA Division

Jongkwan Ko
Quality Management Representative
QA Division