

## CERTIFICATE OF ANALYSIS

**I Product Information:**

Product name: RSV Ag FIA Test  
 Catalog No.: F0186  
 Lot No.: R0830V1A00BV  
 Manufacture date: 2024.08.29  
 Expiration date: 2025.08.28  
 Storage: Room temperature (2-30°C)  
 Extraction buffer: Catalog: SB-F0186, Lot: R0830V1A00BV, Exp.: 2025.08.28

**II Applicable Inspection and Evaluation of Specification:**

**1. Physical Inspection:**

<u>Test Description</u>	<u>Acceptance Criteria</u>	<u>Test Results</u>
a. Label	Ac ≤ 3	0
b. Instruction for Use	Ac ≤ 3	0
c. Sterile swab	Ac ≤ 3	0
d. Sample extraction tube rack	Ac ≤ 3	0
e. Sealed pouch containing pre-filled extraction tubes	Ac ≤ 3	0
f. Extraction tube nozzles	Ac ≤ 3	0
g. SD Card	Ac ≤ 3	0
h. RSV Ag control swabs	Ac ≤ 3	0
i. Pouch	Ac ≤ 3	0
j. Desiccant in the pouch	Ac ≤ 3	0
k. Cassette in the pouch	Ac ≤ 3	0
l. Label on the cassette	Ac ≤ 3	0

*Note: Ac (Acceptance Number) is the maximum allowable defectives in a sample for the lot to be accepted based on the sampling plan.*

**2. Performance Characteristic Inspection:**

<u>Test Description</u>		<u>Criteria</u>	<u>Test Results</u>
a.	LOD	L1 20 replicates	Positive rate 100%
		L2 20 replicates	Positive rate ≥ 95%
		L3 20 replicates	Positive rate ≤ 80%
b.	Specificity	50 clinical nasal samples 50 clinical throat samples	Negative rate ≥ 99%
c.	Control Swab	1 Positive Control Swab	Positive
		1 Negative Control Swab	Negative
d.	Indicator line	Before Use: Display blue indicator line After Use: The blue indicator line disappears	Passed [ <input checked="" type="checkbox"/> ] Failed [ <input type="checkbox"/> ]

**III Comments:**

All data are from QC test of manufacturer unless otherwise indicated.

**IV Safety Certification:**

There are no biohazard materials utilized in this product, no radioactive materials, no narcotic reagents, neither their derivatives, no virus neither their reagent, nor metabolic by-products.

**V Disposition:**

Released [  ]

Rejected [  ]

*Sandy Liu*

Sandy Liu(QA representative)

2024.09.06

Date