

## CERTIFICATE OF ANALYSIS

**I Product Information:**

**Product name:** RSV Ag Rapid Test (cassette)  
**Catalog No.:** R0186C  
**Lot No.:** F1023U6B00BVR2  
**Manufacture date:** 2023.10.17  
**Expiration date:** 2025.10.16  
**Storage:** Room temperature (2-30°C)  
**Extraction buffer:** Catalog: SB-R0186, Lot: S015473-220, Exp.: 2026.09.19  
**RSV Ag control swabs:** Catalog: C0186-SW, Lot: C1017U1, Exp.: 2025.10.16

**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 ≤ 1	0
b. Pouch	Ac ≤ 1	0
c. Desiccant in the pouch	Ac ≤ 1	0
d. Cassette in the pouch	Ac ≤ 1	0
e. Label on the cassette	Ac ≤ 1	0
f. Sealed pouch containing pre-filled extraction tubes	Ac ≤ 1	0
g. Paper rack	Ac ≤ 1	0
h. Insert	Ac ≤ 1	0
i. Swab	Ac ≤ 1	0
j. Nozzle	Ac ≤ 1	0
k. RSV Ag control swabs	Ac ≤ 1	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	R0186-L1 20 replicates R0186-L2 20 replicates R0186-L3 20 replicates	Positive rate=100% Positive rate≥95% Positive rate ≤60%
b. Extraction buffer	SB-R0186 C0186P-SW	100% 100% 15%
c. RSV Ag control swabs	Negative Positive Negative	Negative Positive Negative
d. Specificity	50 clinical samples All negative	All negative All negative
e. Flow rate	Completion of run in membrane	In 3 minutes In 3 minutes

**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)

2024.11.15

Date