

## CERTIFICATE OF ANALYSIS

**I Product Information:**

**Product name:** S. pneumoniae Ag FIA Test  
**Catalog No.:** F0181  
**Lot No.:** RD2136Aa  
**Manufacture date:** 2024-09-20  
**Expiration date:** 2025-09-19  
**Storage:** Room temperature (2-30°C)

**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.                      | Insert                 | Ac ≤ 1                     | 0                   |
| d.                      | Plastic droppers       | Ac ≤ 1                     | 0                   |
| e.                      | Desiccant in the pouch | Ac ≤ 1                     | 0                   |
| f.                      | Cassette in the pouch  | Ac ≤ 1                     | 0                   |
| g.                      | Label on the cassette  | Ac ≤ 1                     | 0                   |
| h.                      | Positive control       | Ac ≤ 1                     | 0                   |
| i.                      | Negative control       | 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                | L1 5 replicates  | Positive rate 100%   |
|                         |                    | L2 5 replicates  | Positive rate ≥ 95%  |
|                         |                    | L3 5 replicates  | Positive rate ≤ 100% |
| b.                      | Negative reference | 35 clinical negative samples<br>1 replicate/sample                                       | Negative rate 100%   |
| c.                      | Positive control   | 2 replicates   | Both positive        |
| d.                      | Negative control   | 2 replicates   | Both negative        |
| e.                      | Indicator line     | Before Use: Display blue indicator line<br>After Use: The blue indicator line disappears | Pass                 |

**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

2024.10.09

QA representative

Date