



CERTIFICATE OF ANALYSIS

This certificate is provided to confirm that the diagnostic kit specified below conforms to the production and testing specifications required by Cepheid's Quality System, in compliance with the US Food and Drug Administration's Quality System Requirements, ISO 13485, European IVD Directive, the Canadian Medical Devices Regulations (CMDR), and the China National Medical Products Administration's Quality System Requirements.

Product Name: Xpert® Xpress Flu/RSV

Cepheid Catalogue Part No.: XPRSFLU/RSV-CN-10

Kit Lot No.: 1001447297

Cartridge Lot No.: 46501

Kit Expiration Date: 2026-08-09

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Solna

Sunnyvale

Lodi

Functional Testing

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|-------------------------|--|--------------------|
| Negative | Flu A NEGATIVE;Flu B NEGATIVE;RSV NEGATIVE | Passed |
| Low Positive | Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE | Passed |
| High Positive | Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE | Passed |

If checked this document is produced electronically and valid without a wet signature.

ThuyTien Nguyen
ThuyTien Nguyen (Sep 24, 2024 10:37 PDT)

Sep 24, 2024

Signature of Quality Assurance, Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist





1001447297

Final Audit Report

2024-09-24

| | |
|-----------------|---|
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