



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.: 1001454117

Cartridge Lot No.: 46509

Kit Expiration Date: 2026-10-04

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 (Oct 22, 2024 15:27 PDT)

Oct 22, 2024

Signature of Quality Assurance, Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist





XPRSFLU.RSV-CN-10 BN 1001454117

Final Audit Report

2024-10-22

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