



## 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.:** 1001449342

**Cartridge Lot No.:** 46502

**Kit Expiration Date:** 2026-09-27

**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 12, 2024 10:21 PDT)

Oct 12, 2024

**Signature of Quality Assurance,                      Date**

**Name:** ThuyTien Nguyen

**Title:** Quality Systems Specialist





# XPRSFLU.RSV-CN-10 BN 1001449342

Final Audit Report

2024-10-12

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