



## 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 and ISO 13485.

**Product Name:** Xpert<sup>®</sup> Xpress CoV-2/Flu/RSV *plus*

**Instructions for Use (IFU)**

**Catalogue Part No.:** XPRS4PLEX-10

**Part No. and Rev.:**

302-8057  Rev  A

**Kit Lot No.:** 1001460325

**Cartridge Lot No.:** 64105

**Kit Expiration Date:** 2025-11-30

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA  
94089 USA

**Manufacturing Facility**

Cepheid  
121 N Guild Avenue  
Lodi, CA 95240  
USA

Solna


Sunnyvale

Lodi

***Functional Testing according to D47377, Rev. L***

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	SARS-CoV-2 NEGATIVE;Flu A NEGATIVE;Flu B NEGATIVE;RSV NEGATIVE	Passed
Positive	SARS-CoV-2 POSITIVE;Flu A POSITIVE;Flu B POSITIVE;RSV POSITIVE	Passed

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

  
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**Signature of Quality Assurance,** **Date**

12DEC2024

**Name:** Betty Thao

**Title:** Quality Systems Specialist