



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[®] Xpress CoV-2/Flu/RSV *plus*

Catalogue Part No.: XPRS4PLEX-10

Kit Lot No.: 1001462624

Cartridge Lot No.: 64409

Kit Expiration Date: 2025-12-21

Instructions for Use (IFU)

Part No. and Rev.:

302-8057 Rev. A

302-8055 Rev. C

303-1854 Rev. B

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 according to D47377, Rev. M

<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.



Signature of Quality Assurance,

01/10/2025

Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist