



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.: 1001462623

Cartridge Lot No.: 64408

Kit Expiration Date: 2025-12-14

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
 Lodi

Sunnyvale

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.

30DEC24

Signature of Quality Assurance,

Date

Name: Tann Tran

Title: Quality Systems Specialist