



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 and the Canadian Devices Regulations.

Product Name: Xpert® Xpress CoV-2/Flu/RSV plus

Cepheid Catalogue Part No.: XP3COV2/FLU/RSV-10

Kit Lot No.: 1001447197

Cartridge Lot No.: 61908

Kit Expiration Date: 2025 09 07

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility

Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA



Solna



Sunnyvale



Newark



Lodi IVD (B2)

Functional Testing

<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.

09 / 19 / 2024

Signature of Quality Assurance, Date

Name: Nhat Dao

Title: Quality Systems Specialist