



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.: 1001465075

Cartridge Lot No.: 31710

Kit Expiration Date: 2026-01-04

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden ■



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.

Anton Engstrom

Anton Engstrom (Jan 15, 2025 12:06 GMT+1)

Signature of Quality Assurance, Date

Name: Anton Andersson Engström

Title: QA Analyst