



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.: 1001455211

Cartridge Lot No.: 30605

Kit Expiration Date: 2025-10-26

Legal Manufacturer

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden ✓

● Solna
Newark

Sunnyvale
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.

Alexander Avramidis
Alexander Avramidis (Nov 6, 2024 13:58 GMT+1)

Signature of Quality Assurance, Date

Name: Alexander Avramidis

Title: QA Analyst