



## 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.:** 1001461287

**Cartridge Lot No.:** 31010

**Kit Expiration Date:** 2025-11-23

**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***

<b><i>Test Description</i></b>	<b><i>Acceptance Criteria</i></b>	<b><i>Test Result</i></b>
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 (Dec 5, 2024 13:19 GMT+1)

**Signature of Quality Assurance,                      Date**

**Name:** Alexander Avramidis

**Title:** QA Analyst