

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.: 1001457801

Cartridge Lot No.: 30622

Kit Expiration Date: 2025-11-09

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.

Samaneh Vahid Gharavi
Samaneh Vahid Gharavi (Dec 3, 2024 16:42 GMT+1)

Signature of Quality Assurance, Date

Name: Samaneh Vahid

Title: Senior QA Analyst