Cepheid

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.: 1000698397

Cartridge Lot No.: 26904

Kit Expiration Date: 2024 01 14

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

Test Description	*Acceptance Criteria*	*Test Result*
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.

26 JAN 2023

Signature of Quality Assurance, **Date**

Name: Theresa Moreno

Title: Quality Systems Specialist