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.: 1001350358

Cartridge Lot No.: 15403

Kit Expiration Date: 2024-04-28

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
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.

12/04/2023

Signature of Quality Assurance, **Date**

Name: Hang Nguyen

Title: Quality Systems Specialist