

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 Na	ame:
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Xpert® Xpress CoV-2/Flu/RSV plus

Cepheid Catalogue Part No.:

XP3COV2/FLU/RSV-10

Kit Lot No.: 1000440324

Cartridge Lot No.: 08328

Kit Expiration Date: 2023-06-18

Solna Newark Sunnyvale Lodi IVD (B2)

Legal Manufacturer

Manufacturing Facility

Cepheid

904 Caribbean Drive

904 Caribbean Drive

Sunnyvale, CA 94089

Sunnyvale, CA 94089

USA

Cepheid

USA

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.

Signature of Quality Assurance,

Name: Jenny Nguyen

Title: Quality Assurance Supervisor