

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.: 1001491163

Cartridge Lot No.: 68107

Kit Expiration Date: 2026 07 05

Legal Manufacturer

Manufacturing Facility

Solna

Sunnyvale Lodi IVD (B2)

Cepheid

Cepheid

121 N Guild Avenue

904 Caribbean Drive Sunnyvale, CA 94089

Lodi, CA 95240

USA

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.

14 J4L 2025 Signature of Quality Assurance,

Date

Name: Meng Mao Thao

Title: Quality Assurance Specialist 1