

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.

Pro	duct	Name:
110	uuci	Maine.

Xpert® Xpress CoV-2/Flu/RSV plus

Cepheid Catalogue Part No.:

XP3COV2/FLU/RSV-10

Kit Lot No.: 1001457657

Cartridge Lot No.: 63614

Kit Expiration Date: 2025 11 16

Legal Manufacturer

Manufacturing Facility

Solna

Newark

Sunnyvale Lodi IVD (B2)

Cepheid

121 N Guild Avenue

904 Caribbean Drive Lodi, CA 95240 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,

Date

Name: Chong Moua

Title: Quality Systems Specialist

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