

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.: 1001449352

Cartridge Lot No.: 62207

Kit Expiration Date: 2025 09 21

Legal Manufacturer

Manufacturing Facility

Solna Newark

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.

Shirid

18 OCT 2022

Signature of Quality Assurance,

Date

Name: Nhat Dao

Title: Quality Systems Specialist