

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.

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Xpert® Xpress CoV-2/Flu/RSV plus

Cepheid Catalogue Part No.:

XP3COV2/FLU/RSV-10

Kit Lot No.: 1000936079

Cartridge Lot No.: 26239

Kit Expiration Date: 2024 05 12

Legal Manufacturer

Manufacturing Facility

)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	cription Acceptance Criteria	
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	

If checked this document is produced electronically and valid without a wet signature.

Signature of Quality Assurance,

20 May 2023
Date

Name: Sayed Safdari

Title: Quality Systems Specialist