Cepheid

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 and ISO 13485.

Product Name: Xpert® Xpress CoV-2/Flu/RSV *plus*

Catalogue Part No.: XPRS4PLEX-10

Kit Lot No.: 1001463045

Cartridge Lot No.: 64006

Kit Expiration Date: 2025-12-07

Instructions for Use (IFU) Part No. and Rev.:
302-8057 Rev. A
302-8055 Rev. C

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA
94089 USA

Manufacturing Facility
Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

○ Solna ○ Sunnyvale
◉ Lodi

Functional Testing according to D47377, Rev. L

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.

Mark Gonzalez 18 DEC 2024

Signature of Quality Assurance **Date**

Name: Mark Gonzalez

Title: Quality Systems Specialist