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 *plus*

Instructions for Use (IFU) Part No. and Rev.:

Catalogue Part No.: XPRS-COV2-10

Kit Lot No.: 1001457884

Cartridge Lot No.: 21205

Kit Expiration Date: 2025 11 16

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 D48538, Rev. K

Test Description	*Acceptance Criteria*	*Test Result*
Negative	SARS-CoV-2 NEGATIVE	Passed
Positive	SARS-CoV-2 POSITIVE	Passed

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

12/23/24

Signature of Quality Assurance, **Date**

Name: Asia Taylor Torres

Title: Quality Systems Specialist