



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*

Catalogue Part No.: XPRS-COV2-10

Kit Lot No.: 1001435017

Cartridge Lot No.: 08414

Kit Expiration Date: 2025 06 08

Instructions for Use (IFU)

Part No. and Rev.:

302-8997 Rev B

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. H.1

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
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.

Signature of Quality Assurance,

6/26/2024

Date

Name: Robert Tucker

Title: Quality Systems Specialist