



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.: 1001443812

Cartridge Lot No.: 09809

Kit Expiration Date: 2025 08 10

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
 Lodi

Sunnyvale

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.

Brandi Fields

Signature of Quality Assurance,

18 Aug 2024

Date

Name: Brandi Fields

Title: Quality Systems Specialist