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.:** 1001463674

**Cartridge Lot No.:** 21110

**Kit Expiration Date:** 2025 12 28

**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.

01/07/25

**Signature of Quality Assurance,** **Date**

**Name:** Asia Torres

**Title:** Quality Assurance Specialist