# 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, ISO 13485, European IVD Directive and the Canadian Devices Regulations.

**Product Name:** Xpert® Xpress CoV-2 *plus*

**Cepheid Catalogue Part No.:** XP3SARS-COV2-10

**Kit Lot No.:** 1001452757

**Cartridge Lot No.:** 20801

**Kit Expiration Date:** 2025-10-12

**Legal Manufacturer**
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

**Manufacturing Facility** ○ Solna ○ Sunnyvale ○ Newark ◉ Lodi
Cepheid
121 N Guild Ave
Lodi, CA 95240 USA

***Functional Testing***

| *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.

**Signature of Quality Assurance,** **Date** 10/26/24

**Name:** Kimberly Perez

**Title:** Quality Systems Specialist