



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.: 1001451799

Cartridge Lot No.: 20506

Kit Expiration Date: 2025-10-05

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
121 N Guild Ave
Lodi, CA 95240 USA

Solna Sunnyvale Newark Lodi

Functional Testing

| <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,

17 OCT 2024

Date

Name: Sayed Safdari

Title: Quality Systems Specialist I