



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.: 1001223839

Cartridge Lot No.: 04926

Kit Expiration Date: 2024 09 15

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
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,

Date

Pauline Vu
Name: Pauline Vu

Title: Quality Systems Specialist