



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.: 1000526149

Cartridge Lot No.: 02010

Kit Expiration Date: 2023-04-16

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility


Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

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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** 10-11-22

Name: Renee Argishti

Title: Sr. Quality Systems Specialist