

## **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.

| Test Description   | Acceptance Criteria   | Test Result  |
|--|---|--------------|
| Functional Testing   |   |              |
| Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 U | Manufacturing Facility Cepheid 904 Caribbean Drive SA Sunnyvale, CA 94089 USA | e Newark Loc |
| Kit Expiration Date:   | 2023-06-25  |              |
| Cartridge Lot No.:   | 01915   |              |
| Kit Lot No.: 10005   | 59136   |              |
| Cepheid Catalogue Par  | t No.: XP3SARS-COV2-10  |              |
| Product Name:  | Xpert® Xpress CoV-2 plus  |              |
| Directive and the Canad  | an Devices Regulations.   |              |

| 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

Name: Molly Doan

Title: Quality Systems Specialist