



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.: 1001449364

Cartridge Lot No.: 20702

Kit Expiration Date: 2025 09 21

<u>Legal Manufacturer</u> Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	<u>Manufacturing Facility</u> <input type="radio"/> Solna <input type="radio"/> Sunnyvale <input type="radio"/> Newark <input checked="" type="radio"/> Lodi Cepheid 121 N Guild Ave Lodi, CA 95240 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,

10/01/2024

Date

Name: Laiza Guevarra

Title: Quality Systems Specialist