Cepheid®

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.: 1000536520

Cartridge Lot No.: 02021

Kit Expiration Date: 2023 04 16

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility ◯ Solna ◉ Sunnyvale ◯ Newark ◯ Lodi
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USA

Functional Testing

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.

DA Samson 03 NOV 22

Signature of Quality Assurance, **Date**

Name: Donna A. Samson

Title: Quality Systems Specialist