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.: 1001173628

Cartridge Lot No.: 13529

Kit Expiration Date: 2024-08-25

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility ◉ Solna ○ Sunnyvale ○ Newark ○ Lodi
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

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.

RoBR3 20230906

Signature of Quality Assurance, **Date**

Name: Robert Fiedler

Title: QA Analyst

© 2022 Cepheid. All rights reserved.