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.: 1001459383

Cartridge Lot No.: 16713

Kit Expiration Date: 2025-11-09

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.

Sara Mustafa Abdulla
Sara Mustafa Abdulla (Nov 21, 2024 11:41 GMT+1)

Signature of Quality Assurance, **Date**

Name: Sara Mustafa Abdulla

Title: QA Analyst