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.: 1001457798

Cartridge Lot No.: 16711

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.

Samaneh Vahid Gharavi
Samaneh Vahid Gharavi (Nov 20, 2024 13:25 GMT+1)

Signature of Quality Assurance, **Date**

Name: Samaneh Vahid

Title: Senior QA Analyst

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