

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.

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Xpert® Xpress CoV-2 plus

Cepheid Catalogue Part No.:

XP3SARS-COV2-10

Kit Lot No.:

1001455053

Cartridge Lot No.:

21101

Kit Expiration Date:

2025-11-02

Legal Manufacturer

Manufacturing Facility Solna Sunnyvale Newark Lodi

Cepheid

Cepheid

904 Caribbean Drive

121 N Guild Ave

Sunnyvale, CA 94089 USA

Lodi, CA 95240 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.

11/10/24

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Title:

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