



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 Medical Devices Regulations (CMDR).

Product Name: Xpert® BCR-ABL Ultra p190

Cepheid Catalogue Part No.: GXBCRABLP190-CE-10

Kit Lot No.: 1001445519

Cartridge Lot No.: 02701

Kit Expiration Date: 2025 04 06

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

Solna

Sunnyvale

Lodi

Functional Testing according to D38418, Rev. G

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	NEGATIVE [Sufficient ABL transcript]	Passed
~0.02% (p190/ABL)	POSITIVE	Passed
~0.1% (p190/ABL)	POSITIVE	Passed

If checked, this document is produced electronically and therefore valid without a wet signature



Signature of Quality Assurance

12/19/2024

Date

Name: Jennifer Nguyen

Title: Quality Systems Specialist