



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.

Product Name: Xpert® BCR-ABL Ultra p190

Cepheid Catalogue Part No.: RBCRABLP190-10

Kit Lot No.: 1001452788

Cartridge Lot No.: 03101

Kit Expiration Date: 2025-10-19

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
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

ThuyTien Nguyen
ThuyTien Nguyen (Nov 5, 2024 14:18 PST)

Nov 5, 2024

Signature of Quality Assurance

Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist





RBCRABLp190-10 1001452788

Final Audit Report

2024-11-05

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