



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.: 1001452787

Cartridge Lot No.: 03102

Kit Expiration Date: 2025-12-28

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

Molly Doan
Molly Doan (Nov 5, 2024 10:02 PST)

Nov 5, 2024

Signature of Quality Assurance

Date

Name: Molly Doan

Title: Quality Systems Specialist





302-7003 Rev C_C of A BCRABLP190, CE-IVD

Final Audit Report

2024-11-05

| | |
|-----------------|--|
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