



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

Cepheid Catalogue Part No.: GXBCRABL-10

Kit Lot No.: 1001449916

Cartridge Lot No.: 42201

Kit Expiration Date: 2025-10-26

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 D16624, Rev. R.1

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	NEGATIVE [Sufficient ABL transcript]	Passed
~0.01%(IS)	POSITIVE	Passed
~0.1%(IS)	POSITIVE	Passed

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

Tann Tran
Tann Tran (Oct 10, 2024 21:59 PDT)

Oct 10, 2024

Signature of Quality Assurance

Date

Name: Tann Tran

Title: Quality Systems Specialist




301-9243 Rev B_ C of A Xpert BCR-ABL Ultra 1001449916

Final Audit Report

2024-10-11

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"301-9243 Rev B_ C of A Xpert BCR-ABL Ultra 1001449916" History

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