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.: 1001447302

Cartridge Lot No.: 42001

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

Test Description	*Acceptance Criteria*	*Test Result*
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 (Sep 25, 2024 15:08 PDT)

Sep 25, 2024

Signature of Quality Assurance **Date**

Name: Tann Tran

Title: Quality Systems Specialist