Cepheid

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 Device Regulations (CMDR).

Product Name: Xpert® BCR-ABL Ultra

Cepheid Catalogue Part No.: GXBCRABL-10

Kit Lot No.: 1001420651

Cartridge Lot No.: 40701

Kit Expiration Date: 2025-06-29

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility ○ Solna ◉ Sunnyvale

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Functional Testing

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

20Mar24

Signature of Quality Assurance **Date**

Name: Molly Doan

Title: Quality Systems Specialist