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.

Product Name: Xpert® BCR-ABL Ultra p190

Cepheid Catalogue Part No.: GXBCRABLP190-CE-10

Kit Lot No.: 1001014836

Cartridge Lot No.: 02001

Kit Expiration Date: 2024-01-28

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility ○ Solna ◉ Sunnyvale ○ Newark ○ Lodi
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
Negative	NEGATIVE [Sufficient ABL transcript]	Passed
~0.02% (p190/ABL)	POSITIVE	Passed
~0.1% (p190/ABL)	POSITIVE	Passed

Tann Tran 27 JUN 23

Signature of Quality Assurance, **Date**

Name: Tann Tran

Title: Quality Systems Specialist