



## 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.

**Product Name:** Xpert® BCR-ABL Ultra p190

**Cepheid Catalogue Part No.:** RBCRABLP190-10

**Kit Lot No.:** 1001457613

**Cartridge Lot No.:** 03103

**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

  
\_\_\_\_\_  
Signature of Quality Assurance

11/27/2024  
\_\_\_\_\_  
Date

**Name:** Jennifer Nguyen

**Title:** Quality Assurance Supervisor