



## 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 p190

**Cepheid Catalogue Part No.:** GXBCRABLP190-CE-10

**Kit Lot No.:** 1001437276

**Cartridge Lot No.:** 02801

**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 D38418, Rev. F**

<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

Molly Doan  
Molly Doan (Jul 30, 2024 09:13 PDT)

Jul 30, 2024

**Signature of Quality Assurance**

**Date**

**Name:** Molly Doan

**Title:** Quality Systems Specialist





# 302-7003 Rev C\_C of A BCRABLP190, CE-IVD

Final Audit Report

2024-07-30

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