



## 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.:

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

Manufacturing Facility

Solna

Sunnyvale

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

*Functional Testing*

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

*Tanja Reed*

Tanja Reed (Jan 3, 2024 06:51 PST)

Jan 3, 2024

Signature of Quality Assurance

Date

Name:

Title:





# 1001406734

Final Audit Report

2024-01-03

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