



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

Cepheid Catalogue Part No.: GXBCRABL-10

Kit Lot No.: 1001443534

Cartridge Lot No.: 41501

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 D16624, Rev. R.1

<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

If checked, this document is produced electronically and therefore valid without a wet signature

Tanja Reed
Tanja Reed (Aug 19, 2024 11:46 PDT)
Signature of Quality Assurance

Aug 19, 2024
Date

Name: Tanja Reed

Title: Quality Systems Specialist





1001443534

Final Audit Report

2024-08-19

Created:	2024-08-19
By:	Tanja Reed (tanja.reed@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAzrzsYe-XP2etB97twzWrLDs_Dj1R4W-

"1001443534" History

-  Document created by Tanja Reed (tanja.reed@cepheid.com)
2024-08-19 - 6:46:10 PM GMT- IP address: 45.62.187.244
-  Document emailed to Tanja Reed (tanja.reed@cepheid.com) for signature
2024-08-19 - 6:46:30 PM GMT
-  Document e-signed by Tanja Reed (tanja.reed@cepheid.com)
Signature Date: 2024-08-19 - 6:46:37 PM GMT - Time Source: server- IP address: 45.62.187.244
-  Agreement completed.
2024-08-19 - 6:46:37 PM GMT