



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® Check

Cepheid Catalogue Part No.: XPERTCHECK-CE-5

Kit Lot No.: 1001424171

Cartridge Lot No.: 06804

Kit Expiration Date: 2026-03-01

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 D14336 Rev. R

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Functional Test	Testing results meet specifications	Passed

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

Molly Doan
Molly Doan (Apr 29, 2024 11:30 PDT)

Apr 29, 2024

Signature of Quality Assurance,

Date

Name: Molly Doan

Title: Quality Systems Specialist





301-6265 Rev B XPERTCHECK

Final Audit Report

2024-04-29

Created:	2024-04-29
By:	Molly Doan (molly.doan@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAF8wMyhYMSQBNdenTBVv-hCauwCcUyJDo

"301-6265 Rev B XPERTCHECK" History

-  Document created by Molly Doan (molly.doan@cepheid.com)
2024-04-29 - 6:29:00 PM GMT- IP address: 45.62.187.64
-  Document emailed to Molly Doan (molly.doan@cepheid.com) for signature
2024-04-29 - 6:30:23 PM GMT
-  Document e-signed by Molly Doan (molly.doan@cepheid.com)
Signature Date: 2024-04-29 - 6:30:57 PM GMT - Time Source: server- IP address: 45.62.187.64
-  Agreement completed.
2024-04-29 - 6:30:57 PM GMT