



## 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.:** 1001442730

**Cartridge Lot No.:** 07101

**Kit Expiration Date:** 2026-05-31

**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 (Aug 27, 2024 13:56 PDT)

Aug 27, 2024

**Signature of Quality Assurance,**

**Date**

**Name:** Molly Doan

**Title:** Quality Systems Specialist





# 301-6265 Rev B XPERTCHECK (2)

Final Audit Report

2024-08-27

Created:	2024-08-27
By:	Molly Doan (molly.doan@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA_qOIJ2LPTZauJWAatDt7hemC3OoauFRD

## "301-6265 Rev B XPERTCHECK (2)" History

-  Document created by Molly Doan (molly.doan@cepheid.com)  
2024-08-27 - 8:56:11 PM GMT- IP address: 45.62.187.244
-  Document emailed to Molly Doan (molly.doan@cepheid.com) for signature  
2024-08-27 - 8:56:36 PM GMT
-  Document e-signed by Molly Doan (molly.doan@cepheid.com)  
Signature Date: 2024-08-27 - 8:56:47 PM GMT - Time Source: server- IP address: 45.62.187.244
-  Agreement completed.  
2024-08-27 - 8:56:47 PM GMT