



## 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® Carba-R

**Cepheid Catalogue Part No.:** GXCARBAR-CN-10

**Kit Lot No.:** 1001414273

**Cartridge Lot No.:** 22403

**Kit Expiration Date:** 2025-07-27

**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 D18272, Rev. AF**

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Low Positive	IMP DETECTED; VIM DETECTED; NDM DETECTED; KPC DETECTED; OXA48 DETECTED	Passed
High Positive	IMP DETECTED; VIM DETECTED; NDM DETECTED; KPC DETECTED; OXA48 DETECTED	Passed
Negative	IMP NOT DETECTED; VIM NOT DETECTED; NDM NOT DETECTED; KPC NOT DETECTED; OXA48 NOT DETECTED	Passed

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

ThuyTien Nguyen  
ThuyTien Nguyen (Feb 13, 2024 12:27 PST)

Feb 13, 2024

Signature of Quality Assurance,

Date

**Name:** ThuyTien Nguyen

**Title:** Quality Systems Specialist





# 1001414273

Final Audit Report

2024-02-13

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