



## 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.:** 1001160150

**Cartridge Lot No.:** 22005

**Kit Expiration Date:** 2025-02-09

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

**Manufacturing Facility**

Solna  Sunnyvale  
 Lodi

**Functional Testing according to D18272, Rev. AE**

<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 (Aug 29, 2023 13:40 PDT)

Aug 29, 2023

Signature of Quality Assurance,

Date

**Name:** ThuyTien Nguyen

**Title:** Quality Systems Specialist





# 1001160150

Final Audit Report

2023-08-29

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