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, the Canadian Medical Devices Regulations (CMDR), and the China National Medical Products Administration's Quality System Requirements.

Product Name: Xpert® Carba-R

Cepheid Catalogue Part No.: GXCARBAR-CN-10

Kit Lot No.: 1001456695

Cartridge Lot No.: 24001

Kit Expiration Date: 2026-04-26

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 D18272, Rev. AF

Test Description	*Acceptance Criteria*	*Test Result*
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 (Nov 8, 2024 15:26 PST)

Nov 8, 2024

Signature of Quality Assurance, **Date**

Name: ThuyTien Nguyen

Title: Quality Systems Specialist

GXCARBAR_CN-10 1001456695

Final Audit Report 2024-11-08

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