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-10

Kit Lot No.: 1001465412

Cartridge Lot No.: 24104

Kit Expiration Date: 2026-06-07

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

Molly Doan
Molly Doan (Dec 30, 2024 13:43 PST)

Dec 30, 2024

Signature of Quality Assurance, **Date**

Name: Molly Doan

Title: Quality Systems Specialist

301-6258 Rev D CofA GXCARBAR

Final Audit Report 2024-12-30

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