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

Catalogue Part No.: GXCARBARP-CE-10

Kit Lot No.: 1001454012

Cartridge Lot No.: 12104

Kit Expiration Date: 2026-04-12

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

(●) Solna ( ) Sunnyvale

Functional Testing

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 valid without a wet signature.

Robert Fiedler
Robert Fiedler (Oct 29, 2024 12:07 GMT+1)

Signature of Quality Assurance **Date**

Name: Robert Fiedler

Title: QA Analyst