



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.: 1001452857

Cartridge Lot No.: 12103

Kit Expiration Date: 2026-04-05

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

<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 valid without a wet signature.

Lava Maroof

Lava Maroof (Oct 21, 2024 13:51 GMT+2)

Signature of Quality Assurance

Date

Name: Lava Maroof

Title: QA Analyst

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