



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.: GXCARBAR-CE-10

Kit Lot No.: 1001451713

Cartridge Lot No.: 12004

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	IMP1 DETECTED; VIM DETECTED, NDM DETECTED; KPC DETECTED; OXA48 DETECTED	Passed
HIGH Positive	IMP1 DETECTED; VIM DETECTED, NDM DETECTED; KPC DETECTED; OXA48 DETECTED	Passed
Negative	IMP1 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.

Alexander Avramidis

Alexander Avramidis (Oct 15, 2024 09:59 GMT+2)

Signature of Quality Assurance

Date

Name: Alexander Avramidis

Title: QA Analyst