Cepheid®

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 Device Regulations (CMDR).

Product Name: Xpert® Carba-R

Cepheid Catalogue Part No.: GXCARBARP-CE-10

Kit Lot No.: 1000579115

Cartridge Lot No.: 10501

Kit Expiration Date: 2024-05-12

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility ◉ Solna ○ Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

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

Anton Andersson 2022-11-20

Signature of Quality Assurance **Date**

Name: Anton Andersson Engström

Title: QA Analyst