# 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

**Cepheid Catalogue Part No.:** GXCARBAR-CN-10

**Kit Lot No.:** 1001370424

**Cartridge Lot No.:** 22205

**Kit Expiration Date:** 2025-05-11

**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

Nov 28, 2023

**Signature of Quality Assurance,** **Date**

**Name:** Tann Tran

**Title:** Quality Systems Specialist