



## 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.:** 1001456537

**Cartridge Lot No.:** 12304

**Kit Expiration Date:** 2026-05-03

**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***

<b><i>Test Description</i></b>	<b><i>Acceptance Criteria</i></b>	<b><i>Test Result</i></b>
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.

Sara Mustafa Abdulla

Sara Mustafa Abdulla (Nov 19, 2024 10:55 GMT+1)

**Signature of Quality Assurance**

**Date**

**Name:** Sara Mustafa Abdulla

**Title:** QA Analyst

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