



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® MRSA NXG

Cepheid Catalogue Part No.: GXMRSA-NXG-10

Kit Lot No.: 1001439645

Cartridge Lot No.: 21801

Kit Expiration Date: 2026-07-21

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

Solna

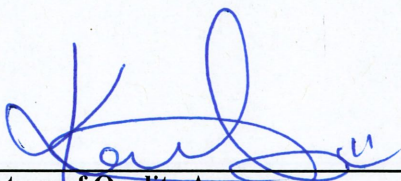
Sunnyvale

Lodi

Functional Testing according to D23916, Rev. U.1

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
LOW Positive	MRSA detected	Passed
HIGH Positive	MRSA detected	Passed
Negative	MRSA not detected	Passed

If checked, this document is produced electronically and therefore valid without a wet signature

 09/18/2024

Signature of Quality Assurance, **Date**

Name: Karla Camarena

Title: Quality Systems Specialist