



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.: 1001459016

Cartridge Lot No.: 21906

Kit Expiration Date: 2026-11-01

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 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

ThuyTien Nguyen
ThuyTien Nguyen (Nov 19, 2024 12:52 PST)
Signature of Quality Assurance,

Nov 19, 2024
Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist





GXMRSA-NXG-10 1001459016

Final Audit Report

2024-11-19

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