



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

Cepheid Catalogue Part No.: GXMRSA-100N-10

Kit Lot No.: 1001452793

Cartridge Lot No.: 25305

Kit Expiration Date: 2026-09-27

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 D16895, Rev. AA

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	MRSA Positive	Passed
Negative	MRSA Negative	Passed

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

Tann Tran

Tann Tran (Oct 21, 2024 23:00 PDT)

Oct 21, 2024

Signature of Quality Assurance,

Date

Name: Tann Tran

Title: Quality Systems Specialist





301-5505 GX MRSA CoA Rev B 1001452793

Final Audit Report

2024-10-22

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