Cepheid®

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.: 1001462603

Cartridge Lot No.: 22705

Kit Expiration Date: 2026 11 29

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

Test Description	*Acceptance Criteria*	*Test Result*
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

Signature of Quality Assurance, 16 Dec 2024 **Date**

Name: Nancy Inthavisak

Title: Quality Systems Specialist