

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-CE-10

Kit Lot No.: 1001446999

Cartridge Lot No.: 13602

Kit Expiration Date: 2026-09-06

Legal Manufacturer

Manufacturing Facility

Cepheid

904 Caribbean Drive

Sunnyvale, CA 94089 USA

Cepheid AB

Röntgenvägen 5

SE-171 54 Solna

Sweden

Solna

Lodi

Sunnyvale

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,

20240923

Name: Mustafa Didehvar

Title:

OA Analyst