# 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.:** 1001455172

**Cartridge Lot No.:** 13901

**Kit Expiration Date:** 2026-10-25

**Legal Manufacturer**
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

**Manufacturing Facility**
Cepheid AB
Röntgenvägen 5
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(●) 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

Lava Maroof
Lava Maroof (Nov 11, 2024 13:32 GMT+1)

**Signature of Quality Assurance,** **Date**

**Name:** Lava Maroof

**Title:** QA Analyst