

## **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                                     | 1-100N-10 ▼                                                          |             |          |
| Kit Lot No.: 1001028472                                                |                                                                      |             |          |
| Cartridge Lot No.: 24010                                               |                                                                      |             |          |
| Kit Expiration Date: 2025 02 23                                        |                                                                      |             |          |
| Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA | Manufacturing Facility Cepheid 121 N Guild Avenue Lodi, CA 95240 USA | Solna  Lodi | Sunnyval |
| Functional Testing according to D168                                   | 395, Rev. AA                                                         |             |          |

| Test Description | Acceptance Criteria | Test Result |
|------------------|---------------------|-------------|
| Positive         | MRSA Positive       | Passed      |
| Negative         | MRSA Negative       | Passed      |

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

Signature of Quality Assurance,

Date

Name: Crystal Sysenglath

Title: Quality Systems Specialist