



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/SA Blood Culture

Cepheid Catalogue Part No.: GXM RSA/SABC-CE-10

Kit Lot No.: 1001410999

Cartridge Lot No.: 20902

Kit Expiration Date: 2025-09-21

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Solna

Sunnyvale

Lodi

Functional Testing according to D36872, Rev. H

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|-------------------------|----------------------------|--------------------|
| Positive | MRSA Positive; SA Positive | Passed |
| Negative | MRSA Negative; SA Negative | Passed |

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



Signature of Quality Assurance,

1/23/2024

Date

Name: Hang Nguyen

Title: Quality Systems Specialist