



## 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.:** GXMRSA/SABC-CE-10

**Kit Lot No.:** 1001435302

**Cartridge Lot No.:** 21501

**Kit Expiration Date:** 2026-03-29

**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

Zenny Santos Digitally signed by Zenny Santos  
Date: 2024.07.16 16:08:36 -07'00'

Jul 16, 2024

Signature of Quality Assurance,

Date

**Name:** Zenny Santos

**Title:** Quality Systems Specialist