

## **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/SA-BC-10

Kit Lot No.: 1001452749

Cartridge Lot No.: 22101

Kit Expiration Date: 2026 03 29

Legal Manufacturer

Cepheid

904 Caribbean Drive

Sunnyvale, CA 94089 USA

**Manufacturing Facility** 

Cepheid

121 N Guild Avenue

Lodi, CA 95240

USA

Solna

Sunnyvale

Lodi

## Functional Testing according to D36872, Rev. H

Test Description	Acceptance Criteria	Test Result
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,

11 | 1 | 20 24 Date

Name: Laiza Guevarra

Title: Quality

Quality Systems Specialist