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.: 1001456692

Cartridge Lot No.: 22102

Kit Expiration Date: 2026-10-25

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

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

Molly Doan
Molly Doan (Nov 20, 2024 10:17 PST)

Nov 20, 2024

Signature of Quality Assurance, **Date**

Name: Molly Doan

Title: Quality Systems Specialist

302-0555 Rev B CofA MRSASABC-CE

Final Audit Report 2024-11-20

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