



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 Japanese Pharmaceuticals and Medical Devices Law and ISO 13485.

Product Name: Xpert® MRSA/SA BC

Cepheid Catalogue Part No.: GXMRSA-BC-JP-10

Kit Lot No.: 1001456693

Cartridge Lot No.: 22103

Kit Expiration Date: 2026-05-03

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA



Solna



Sunnyvale



Lodi

Functional Testing

according to D33080, Rev. D

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
MRSA(H) POSITIVE	MRSA POSITIVE; SA POSITIVE	Passed
MRSA(L) POSITIVE	MRSA POSITIVE; SA POSITIVE	Passed
MSSA(H) POSITIVE	MRSA NEGATIVE; SA POSITIVE	Passed
MSSA(L) POSITIVE	MRSA NEGATIVE; SA POSITIVE	Passed
Negative	MRSA NEGATIVE; SA NEGATIVE	Passed

Final Judgement

<i>Product Specification</i>	<i>Judgement</i>
<i>Sensitivity</i>	Passed
<i>Precision</i>	Passed
<i>Simultaneous Repeatability</i>	Passed

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

Molly Doan
Molly Doan (Nov 21, 2024 13:18 PST)

Nov 21, 2024

Signature of Quality Assurance,

Date

Name: Molly Doan

Title: Quality Systems Specialist





302-0160 Rev C

Final Audit Report

2024-11-21

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