



## 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.:** 1001452783

**Cartridge Lot No.:** 21902

**Kit Expiration Date:** 2026-04-05

**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 Dec 10, 2024 14:29 PST

Dec 10, 2024

**Signature of Quality Assurance,**

**Date**

**Name:** Molly Doan

**Title:** Quality Systems Specialist





# 302-0160 Rev C

Final Audit Report

2024-12-10

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