



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 SSTI

Catalogue Part No.: GXMRSA/SA-SSTI-CE

Kit Lot No.: 1001462472

Cartridge Lot No.: 16503

Kit Expiration Date: 2026-10-04

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Functional Testing

<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 valid without a wet signature.

Samaneh Vahid Gharavi
Samaneh Vahid Gharavi (Dec 20, 2024 11:27 GMT+1)

Signature of Quality Assurance

Date

Name: Samaneh Vahid

Title: Senior QA Analyst