

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.: 1001461226

Cartridge Lot No.: 16601

Kit Expiration Date: 2026-03-15

Legal Manufacturer Manufacturing Facility

Cepheid ABCepheid ABRöntgenvägen 5Röntgenvägen 5SE-171 54 Solna,SE-171 54 Solna,

Sweden Sweden

Functional Testing

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 valid without a wet signature.

Samaneh Vahid Gharavi (Dec 13, 2024 13:58 GMT+1) Signature of Quality Assurance	Date
Samaneh Vahid Gharavi	

Name: Samaneh Vahid

Title: Senior QA Analyst