

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

Cepheid Catalogue Part No.:

Kit Lot No.: 1000871869

Cartridge Lot No.: 23907

Kit Expiration Date: 2025 02 09

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility


Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

- Solna Sunnyvale
 Lodi

Functional Testing according to D16895, Rev. AA

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	MRSA Positive	Passed
Negative	MRSA Negative	Passed

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



 Signature of Quality Assurance, 20 APR 23
Date

Name: Crystal Sysenglath

Title: Quality Systems Specialist