

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.: GXMRSA-100N-10	•
Kit Lot No.: 1001407523	
Cartridge Lot No.: 24502	
Kit Expiration Date: 2025 12 21	

Legal Manufacturer	Manufacturing Facility		
Cepheid	Cepheid	Solna	Sunnyvale
904 Caribbean Drive	121 N Guild Avenue	Sollia	Sulliyvaic
Sunnyvale, CA 94089 USA	Lodi, CA 95240	_	
	USA	Lodi	

Functional Testing according to D16895, Rev. AA

Test Description	Acceptance Criteria	Test Result
Positive	MRSA Positive	Passed
Negative	MRSA Negative	Passed

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

USA

Name: Brandi Fields

Title: Quality Systems Specialist