

Product Name: Xpert® MRSA

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 Device Regulations (CMDR).

Cepheid Catalogue Part No.: GXMRSA-100N-10		
Kit Lot No.: 1000693143		
Cartridge Lot No.: 23809		
Kit Expiration Date: 2025-01-05		
Legal Manufacturer	Manufacturing Facility	Sunnyvale
Cepheid	Cepheid	
904 Caribbean Drive	904 Caribbean Drive	
Sunnyvale, CA 94089 USA	Sunnyvale, CA 94089 USA	
Functional Testing		

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

Aus finner	01/25/23
Signature of Quality Assurance	Date
Name: Austin Mei	
Title: Quality System Specialist	