

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).

Product Name: Xpert® MRSA			
Cepheid Catalogue Part No.: GXMRSA-100N-10			
Kit Lot No.: 1000767467			
Cartridge Lot No.: 23815			
Kit Expiration Date: 2025-02-09			
Legal Manufacturer	Manufacturing Facility	Solna	♠ Sunnyvale
Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA		

Functional Testing

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

DASm-	10 MAR 23
Signature of Quality Assurance	Date
Name: Donna A. Samson	
Title: Quality Systems Specialist	