

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).

	and an interior Bettee Regulation	(01/12/14)	
Product Name: Xpert® MRSA/SA Blood Culture			
Cepheid Catalogue Part No.: GXMRSA/SABC-CE-10			
Kit Lot No.: 1001	160078		
Cartridge Lot No.: 20	703		
Kit Expiration Date: 2	2025-05-11		
Legal Manufacturer		Manufacturing Facility O Solna	
Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden		Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	
Functional Testing			
Test Description	Acceptance Criteria		Test Result
Positive	MRSA Positive; SA Positive		Passed
Negative	MRSA Negative; SA Negative		Passed

Signature of Quality Assurance Bate

Name: Molly Doan

Title: Quality Systems Specialist