

## **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 dian Medical Devices	Quality System Requirements, ISO 13485, European IVD Dir Regulations (CMDR).	ective and the Cana-	
Product Name: Xpe	ert® MRSA/SA Blood Culture		
Cepheid Catalogue P	art No.:GXMRSA/SABC-CE-10		
Kit Lot No.: 100140	2807		
Cartridge Lot No.: 2	20801		
Kit Expiration Date:	2025-07-06		
Legal Manufacture Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden	Manufacturing Facility Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	) Solna •	Sunnyvale
Functional Testing	according to D36872, Rev. H		
Functional Testing  Test Description	Acceptance Criteria	Test Result	1
		Test Result Passed	]
Test Description	Acceptance Criteria		
Test Description  Positive  Negative	Acceptance Criteria  MRSA Positive; SA Positive  MRSA Negative; SA Negative  comment is produced electronically and therefore valid without	Passed Passed	
Test Description  Positive Negative  If checked, this do	Acceptance Criteria  MRSA Positive; SA Positive  MRSA Negative; SA Negative  comment is produced electronically and therefore valid without  12 08 2033  y Assurance,  Date	Passed Passed	

Quality Assurance Supervisor