

Signature of Quality Assurance

Michael Lee

Quality Systems Specialist

Name:

Title:

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).

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Product Name: Xpert® MR	SA NXG		
Cepheid Catalogue Part No	o.: GXMRSA-NXG-CE-10		
Kit Lot No.: 100062808	37	~	
Cartridge Lot No.: 07916			
Kit Expiration Date: 2024-	12-01		
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA		Manufacturing Facility Soln Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	a Sunnyvale
Functional Testing			
Test Description	Acceptance Criteria		Test Result
LOW Positive	MRSA detected		Passed
HIGH Positive	MRSA detected		Passed
Negative	MRSA not detected		Passed
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Michaeler 12/30/2022			

Date