

## 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 Devices Regulations (CMDR).

Kit Lot No.: 1001425421			
Cartridge Lot No.: 21202			
Kit Expiration Date: 2026 04 12		,	
Legal Manufacturer	Manufacturing Facility		
Cepheid	Cepheid	Solna	Sunnyvale
904 Caribbean Drive	121 N Guild Avenue	John	Juniy vale

Lodi, CA 95240

**USA** 

## Functional Testing according to D23916, Rev. U

Product Name: Xpert® MRSA NXG

Sunnyvale, CA 94089 USA

Cepheid Catalogue Part No.: GXMRSA-NXG-10

Test Description	Acceptance Criteria	Test Result
LOW Positive	MRSA detected	Passed
HIGH Positive	MRSA detected	Passed
Negative	MRSA not detected	Passed

If checked, this document is produced electronically and therefore valid without a wet signature

Signature of Quality Assurance,

4/29/24 Date

Name: Trinh Nguyen

Title: Quality Systems Specialist

Lodi