

## **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).

dian Medical Devices Regulati	ons (CMDR).	Scan IVD Directive and the Cana-
Product Name: Xpert® SA	Nasal Complete	
Cepheid Catalogue Part No.:	GXSACOMP-10	
Kit Lot No.: 1001437281		
Cartridge Lot No.: 28502		
Kit Expiration Date: 2026-0	8-09	
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA  Functional Testing according	Manufacturing Facilit Cepheld 904 Caribbean Drive Sunnyvale, CA 94089 USA ug to D36872 Rev. H	Solna Sunnyvale
Test Description	Acceptance Criteria	Test Result
Positive	MRSA Positive; SA Positive	Passed
Negative	MRSA Negative; SA Negative	Passed
Molly Doan	is produced electronically and therefore very like the second of the sec	valid without a wet signature
Molly Doan (Nov 6, 2024 10:57 PST)  Signature of Quality Assura	<u> </u>	<u> </u>
6	,	

Name: MollyDoan

Title: Quality Systems Specialist

## 301-6217 Rev B SACOMP

Final Audit Report 2024-11-06

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By: Molly Doan (molly.doan@cepheid.com)

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