



## 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).

**Product Name:** Xpert® SA Nasal Complete

**Catalogue Part No.:** GXSACOMP-CE-10

**Kit Lot No.:** 1001461113

**Cartridge Lot No.:** 29102

**Kit Expiration Date:** 2026-11-15

**Legal Manufacturer**

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna  
Sweden

**Manufacturing Facility**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
USA

Solna

Sunnyvale

***Functional Testing***

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	MRSA POSITIVE; SA POSITIVE	Passed
Negative	MRSA NEGATIVE; SA NEGATIVE	Passed

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

ThuyTien Nguyen  
ThuyTien Nguyen (Dec 7, 2024 14:18 PST)

Dec 7, 2024

**Signature of Quality Assurance**

**Date**

**Name:** ThuyTien Nguyen

**Title:** Quality Systems Specialist





# GXSACOMP-CE-10 1001461113

Final Audit Report

2024-12-07

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