



## 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

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

**Kit Lot No.:** 1001455927

**Cartridge Lot No.:** 28902

**Kit Expiration Date:** 2026-10-18

**Legal Manufacturer**

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

**Manufacturing Facility**

Solna       Sunnyvale  
 Lodi

**Functional Testing according to D36872 Rev. H**

<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 therefore valid without a wet signature

ThuyTien Nguyen  
ThuyTien Nguyen (Oct 31, 2024 13:17 PDT)  
**Signature of Quality Assurance,**

Oct 31, 2024  
**Date**

**Name:** ThuyTien Nguyen

**Title:** Quality Systems Specialist





# GXSACOMP-10 1001455927

Final Audit Report

2024-10-31

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