



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.: 1001452782

Cartridge Lot No.: 28801

Kit Expiration Date: 2026-09-27

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA



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

Tann Tran

Tann Tran (Oct 16, 2024 21:36 PDT)

Oct 16, 2024

Signature of Quality Assurance,

Date

Name: Tann Tran

Title: Quality Systems Specialist





301-6217 Rev B SACOMP 1001452782

Final Audit Report

2024-10-17

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