



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.: 1001461109

Cartridge Lot No.: 29101

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 3, 2024 16:29 PST)

Dec 3, 2024

Signature of Quality Assurance

Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist





GXSACOMP-CE-10 1001461109

Final Audit Report

2024-12-04

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