

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.: 1001456545

Cartridge Lot No.: 16502

Kit Expiration Date: 2026-07-26

Legal	Manufacturer
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Cepheid AB Röntgenvägen 5 SE-171 54 Solna

Sweden

Manufacturing Facility

Solna

Sunnyvale

Cepheid AB Röntgenvägen 5 SE-171 54 Solna

Sweden

Functional Testing

Test Description	Acceptance Criteria	Test Result
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.

Signature of Quality Assurance

Date

Name: Lava Maroof

Title: QA Analyst

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