

## **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.: 1001453994

Cartridge Lot No.: 16304

Kit Expiration Date: 2026-07-26

Legal Manufacturer

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.

ROBERT FIEDLER

20241030

Signature of Quality Assurance

Date

Name: Robert Fiedler

Title: QA Analyst

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