

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.: 1001457605
Cartridge Lot No.: 28906
Kit Expiration Date: 2026-11-01

Legal Manufacturer	Manufacturing Facility		
Cepheid	Cepheid	Solna	Sunnyvale
904 Caribbean Drive	904 Caribbean Drive	Soma	Samiyyane
Sunnyvale, CA 94089 USA	Sunnyvale, CA 94089		
	USA	Lodi	

Functional Testing according to D36872 Rev. H

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 therefore valid without a wet signature

Signature of Quality Assurance,

Date

Name: Jennifer Nguyen

Title: Quality Assurance Supervisor