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® Xpress Strep A

Cepheid Catalogue Part No.: XPRSTREPA-10

Kit Lot No.: 1001463631

Cartridge Lot No.: 41506

Kit Expiration Date: 2025-12-21

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility
Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

○ Solna ○ Sunnyvale

◉ Lodi

Functional Testing according to D27089, Rev. R

Test Description	*Acceptance Criteria*	*Test Result*
Negative	Strep A NOT DETECTED	Passed
LOW Positive	Strep A DETECTED	Passed
HIGH Positive	Strep A DETECTED	Passed

☐ If checked, this document is produced electronically and therefore valid without a wet signature

Signature of Quality Assurance, **Date** 30 Dec 2024

Name: Nancy Inthavisak

Title: Quality Systems Specialist