



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

Catalogue Part No.: XPRSTREPA-CE-10

Kit Lot No.: 1001460362

Cartridge Lot No.: 41201

Kit Expiration Date: 2025-11-30

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

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>
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 valid without a wet signature.

Zenny Santos
Zenny Santos (Dec 12, 2024 15:11 PST)

Dec 12, 2024

Signature of Quality Assurance

Date

Name: Zenny Santos

Title: Quality Systems Specialist