



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.: 1001450724

Cartridge Lot No.: 40812

Kit Expiration Date: 2025-10-12

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

| <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 therefore valid without a wet signature

Signature of Quality Assurance,

21 Oct 2024

Date

Name: Sarah Bagasol

Title: Quality Assurance Specialist