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.: 1001448669

Cartridge Lot No.: 11508

Kit Expiration Date: 2025-08-31

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufacturing Facility
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

(●) 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

Cemf 20240930

Signature of Quality Assurance, **Date**

Name: Lava Maroof

Title: QA Analyst