# 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.:** 1001464240

**Cartridge Lot No.:** 11220

**Kit Expiration Date:**2025-12-14

**Legal Manufacturer**
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

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

(●) Solna ( ) Sunnyvale

***Functional Testing***

| *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 valid without a wet signature.

Lava Maroof
Lava Maroof (Dec 24, 2024 14:52 GMT+1)

**Signature of Quality Assurance** **Date**

**Name:** Lava Maroof

**Title:** QA Analyst