# 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® C.difficile/Epi

**Cepheid Catalogue Part No.:** GXCDIFF/EPI-10

**Kit Lot No.:** 1001461384

**Cartridge Lot No.:** 42203

**Kit Expiration Date:** 2026-06-07

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

**Manufacturing Facility**
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

○ Solna ● Sunnyvale

○ Lodi

***Functional Testing according to D37468, Rev.*** E.1

| *Test Description* | *Acceptance Criteria* | *Test Result* |
|---|---|---|
| Positive | Toxigenic C.diff POSITIVE; 027 PRESUMPTIVE POSITIVE | Passed |
| Negative | Toxigenic C.diff NEGATIVE; 027 PRESUMPTIVE NEGATIVE | Passed |

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

Molly Doan
Molly Doan (Jan 2, 2025 09:37 PST)

Jan 2, 2025

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

**Name:** Molly Doan

**Title:** Quality Systems Specialist

# 301-6247 Rev B CofA CDIFF-EPI (2)

Final Audit Report 2025-01-02

| | |
|---|---|
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