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.: 1001461385

Cartridge Lot No.: 42204

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 09:38 PST)

Jan 2, 2025

Signature of Quality Assurance, **Date**

Name: Molly Doan

Title: Quality Systems Specialist

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Final Audit Report 2025-01-02

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