



## 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.:** 1001448215

**Cartridge Lot No.:** 41603

**Kit Expiration Date:** 2026 03 15

**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 D37468, Rev. E.1**

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
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

09/26/2024

Signature of Quality Assurance,

Date

**Name:** Crystal Sysenglath

**Title:** Quality Systems Specialist