



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.: 1001450422

Cartridge Lot No.: 41204

Kit Expiration Date: 2026-03-15

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

<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

Molly Doan
Molly Doan (Oct 1, 2024 12:20 PDT)

Oct 1, 2024

Signature of Quality Assurance,

Date

Name: Molly Doan

Title: Quality Systems Specialist





301-6247 Rev B CofA CDIFF-EPI

Final Audit Report

2024-10-01

Created:	2024-10-01
By:	Molly Doan (molly.doan@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAz3TfcbSgppqUEcUN4E4rgW3JhQzPR_OOH

"301-6247 Rev B CofA CDIFF-EPI" History

-  Document created by Molly Doan (molly.doan@cepheid.com)
2024-10-01 - 7:19:54 PM GMT- IP address: 45.62.187.255
-  Document emailed to Molly Doan (molly.doan@cepheid.com) for signature
2024-10-01 - 7:20:46 PM GMT
-  Document e-signed by Molly Doan (molly.doan@cepheid.com)
Signature Date: 2024-10-01 - 7:20:55 PM GMT - Time Source: server- IP address: 45.62.187.255
-  Agreement completed.
2024-10-01 - 7:20:55 PM GMT