



## 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 BT

**Catalogue Part No.:** GXCDIFFBT-CE-10

**Kit Lot No.:** 1001460197

**Cartridge Lot No.:** 37401

**Kit Expiration Date:**2026-05-24

**Legal Manufacturer**

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna,  
Sweden

**Manufacturing Facility**

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna,  
Sweden

***Functional Testing***

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive Control	Toxigenic C.diff POS;Binary Toxin POS;027 PRESUMPTIVE POS	Passed
Negative Control	Toxigenic C.diff NEG;Binary Toxin NEG;027 NEG	Passed

If checked this document is produced electronically and valid without a wet signature.

Robert Fiedler  
Robert Fiedler (Dec 5, 2024 11:36 GMT+1)

**Signature of Quality Assurance**

**Date**

**Name:** Robert Fiedler

**Title:** QA Analyst