



## 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 Device Regulations (CMDR).

Product Name: Xpert® C. difficile BT

Cepheid Catalogue Part No.: GXCDIFFBT-CE-10

Kit Lot No.: 1000649234

Cartridge Lot No.: 34901

Kit Expiration Date: 2024-06-23

Legal Manufacturer

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna  
Sweden

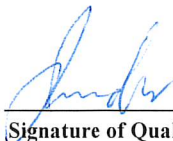
Manufacturing Facility

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna  
Sweden

Solna  Sunnyvale

*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

 2023-01-02

Signature of Quality Assurance

Date

Name: Alexander Avramidis

Title: QA Analyst