



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.:

Cartridge Lot No.:

Kit Expiration Date:

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

Caruf 2024 05 08

Signature of Quality Assurance

Date

Name:

Title: