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.: 1001493705

Cartridge Lot No.: 38302

Kit Expiration Date:2027-01-24

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Manufacturing Facility
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
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.

William Palmén
William Palmén (Aug 14, 2025 11:24:30 GMT+2)

Aug 14, 2025

Signature of Quality Assurance **Date**

Name: William Palmén

Title: QA Analyst