

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.: 1001477727

Cartridge Lot No.: 37902

Kit Expiration Date: 2026-09-13

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.

Lava Maroof
Lava Maroof (Apr 1, 2025 12:54 GMT+2)

Signature of Quality Assurance

Date

Name: Lava Maroof

Title: QA Analyst