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, the Canadian Medical Devices Regulations (CMDR) and the China National Medical Products Administration's Quality System Requirements.

Product Name: Xpert® *C.difficile*

Cepheid Catalogue Part No.: GXCDIFFICILE-CN-10

Kit Lot No.: 1001454002

Cartridge Lot No.: 37203

Kit Expiration Date: 2026-04-19

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility
Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Functional Testing according to D37468 Rev: E.1

Test Description	*Acceptance Criteria*	*Test Result*
Positive Control	Toxigenic C.diff POSITIVE; 027 PRESUMPTIVE POS	Passed
Negative Control	Toxigenic C.diff NEGATIVE; 027 PRESUMPTIVE NEG	Passed

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

Robert Fiedler
Robert Fiedler (Nov 6, 2024 15:17 GMT+1)

Signature of Quality Assurance, **Date**

Name: Robert Fiedler

Title: QA Analyst