



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

Catalogue Part No.: GXCDIFFICILE-CE-10

Kit Lot No.: 1001455171

Cartridge Lot No.: 37301

Kit Expiration Date: 2026-04-26

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Functional Testing

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	Toxigenic C.diff POSITIVE; 027 PRESUMPTIVE POS	Passed
Negative	Toxigenic C.diff NEGATIVE; 027 PRESUMPTIVE NEG	Passed

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

Samaneh Vahid Gharavi

Samaneh Vahid Gharavi (Nov 18, 2024 16:09 GMT+1)

Signature of Quality Assurance

Date

Name: Samaneh Vahid

Title: Senior QA Analyst