

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 Japanese Pharmaceuticals and Medical Devices Law and ISO 13485.

Product Name: Xpert® C. difficile

Cepheid Catalogue Part No.: GXCDIFF-JP-10

Kit Lot No.: 1001454001

Cartridge Lot No.: 37202

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

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

Final Judgement

<i>Product Specification</i>	<i>Judgement</i>
Sensitivity	Passed
Precision	Passed
Simultaneous Repeatability	Passed

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

Robert Fiedler

Robert Fiedler (Nov 4, 2024 09:25 GMT+1)

Signature of Quality Assurance

Date

Name: Robert Fiedler

Title: QA Analyst