



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/Epi

Cepheid Catalogue Part No.: GXCDIFF/EPI-10

Kit Lot No.: 1001459509

Cartridge Lot No.: 42001

Kit Expiration Date: 2026-05-10

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

Solna

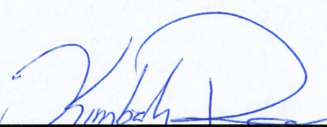
Sunnyvale

Lodi

Functional Testing according to D37468, Rev. E.1

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

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



Signature of Quality Assurance,

11/21/24

Date

Name: Kimberly Perez

Title: Quality Systems Specialist