



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 13485:2003, IVDD and the Canadian Devices Regulations.

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Product Name: Xpert C. difficile BT

Cepheid Catalogue Part #: GXCDIFFBT-CE-10

Lot #: 1000135242 / 30808

Expiration Date: 2020-04-12

Functional Testing

| <i>Test Description</i> | <i>Acceptance Criteria (n=30)</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 |

Based on a review of the test results and the manufacturing documentation, this Kit is released for distribution.



Signature of Quality Assurance, Date

Name: Kambiz Ghaderi

Title: QA Analyst