



## 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 #:** 1000111401 / 30904

**Expiration Date:** 2020-03-01

### *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.*

 20180924

**Signature of Quality Assurance, Date**

**Name:** Samaneh Vahid

**Title:** QA Analyst