

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 #: 31605/1000152257

Expiration Date: 2020-10-04

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.

 20190424
Signature of Quality Assurance, Date

Name: Marie Bah

Title: QA Manager Release