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 Device Regulations (CMDR).

Product Name: Xpert® C. difficile BT

Cepheid Catalogue Part No.: GXCDIFFBT-CE-10

Kit Lot No.: 1000179827

Cartridge Lot No.: 32403

Kit Expiration Date: 2021-05-30

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Manufacturing Facility (•) Solna ( ) Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
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

20191219

Signature of Quality Assurance **Date**

Name: Marie Bah

Title: QA Manager Release