Cepheid®

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® CT/NG

Cepheid Catalogue Part No.: GXCT/NG-CE-10

Kit Lot No.: 1000170213

Cartridge Lot No.: 31315

Kit Expiration Date: 2021-02-28

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility ◉ Solna ○ Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
Positive	CT detected; NG detected	Passed
Negative	CT not detected; NG not detected	Passed

20191216

Signature of Quality Assurance **Date**

Name: Marie Bah

Title: QA Manager Release