



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.: 1000322204

Cartridge Lot No.: 33508

Kit Expiration Date: 2023-10-15

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

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	CT detected; NG detected	Passed
Negative	CT not detected; NG not detected	Passed

Signature of Quality Assurance

2021-10-29

Date

Name: Eleni Vangeli

Title: QA Analyst