



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 Devices Regulations (CMDR).

Product Name: Xpert® CT/NG

Cepheid Catalogue Part No.: GXCT/NG-10

Kit Lot No.: 1001457795

Cartridge Lot No.: 36213

Kit Expiration Date: 2026-11-08

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94809 USA

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden



Solna



Sunnyvale



Lodi

Functional Testing according to D16904, Rev. AL.1

<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

If checked, this document is produced electronically and therefore valid without a wet signature

Robert Fiedler

Robert Fiedler (Nov 21, 2024 12:41 GMT+1)

Signature of Quality Assurance,

Date

Name: Robert Fiedler

Title: QA Analyst