

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, the Canadian Medical Devices Regulations (CMDR) and the China National Medical Products Administration's Quality System Requirements.

Product Name: Xpert® CT/NG

Catalogue Part No.: GXCT/NGX-CE-10

Kit Lot No.: 1001455201

Cartridge Lot No.: 36207

Kit Expiration Date: 2026-10-18

<u>Legal Manufacturer</u> <u>Manufacturing Facility</u>

Solna

Sunnyvale

Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden

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

✓ If checked this document is produced electronically and valid without a wet signature.

Signature of Quality Assurance	Date
Samaneh Vahid Gharavi Samaneh Vahid Gharavi (Nov 4, 2024 12:50 GMT+1)	

Name: Samaneh Vahid

Title: Senior QA Analyst