

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.: 1001454039

Cartridge Lot No.: 36115

Kit Expiration Date: 2026-10-18

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

● Solna Sunnyvale

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

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

Mustafa Didehvar
Mustafa Didehvar (Nov 1, 2024 12:43 GMT+1)

Signature of Quality Assurance

Date

Name: Mustafa Didehvar

Title: QA Analyst