

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 Japanese Pharmaceuticals and Medical Devices Law and ISO 13485.

Product Name: Xpert® CT/NG

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

Kit Lot No.: 1001461260

Cartridge Lot No.: 36215

Kit Expiration Date: 2026-11-22

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Manufacturing Facility

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna,
Sweden

Functional Testing

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
LOW Positive	CT DETECTED;NG DETECTED	Passed
MEDIUM Positive	CT DETECTED;NG DETECTED	Passed
HIGH Positive	CT DETECTED;NG DETECTED	Passed
Negative	CT NOT DETECTED; NG NOT DETECTED	Passed

Final Judgement

<i>Product Specification</i>	<i>Judgement</i>
Sensitivity	Passed
Precision	Passed
Simultaneous Repeatability	Passed

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

Alexander Avramidis

Alexander Avramidis (Dec 6, 2024 14:49 GMT+1)

Signature of Quality Assurance

Date

Name: Alexander Avramidis

Title: QA Analyst