

## **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.: 1001457504

Cartridge Lot No.: 36209

**Kit Expiration Date: 2026-10-25** 

Legal Manufacturer Manufacturing Facility

Cepheid AB Röntgenvägen 5 SE-171 54 Solna Solna

Sunnyvale

Sweden Sweden

## **Functional Testing**

Cepheid AB

Röntgenvägen 5

SE-17154 Solna

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.

Lava Maroof (Nov 13, 2024 10:43 GMT+1)

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