

## **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.: 1001456492

Cartridge Lot No.: 36208

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

Legal Manufacturer Manufacturing Facility Solna Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Sweden 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	
Lava Maroof (Nov 11, 2024 12:51 GMT+1)		
Lava Maroof		

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Title: QA Analyst