

## **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/NG-CE-10

Kit Lot No.: 1001480834

Cartridge Lot No.: 36516

**Kit Expiration Date: 2027-04-04** 

<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.

Mustafa Didehvar  Mustafa Didehvar (May 2, 2025 08:49 GMT+2)		
Signature of Quality Assurance	Date	

Name: Mustafa Didehvar

Title: QA Analyst