Cepheid®

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 and the Canadian Medical Devices Regulations (CMDR).

Product Name: Xpert® CT/NG

Cepheid Catalogue Part No.: GXCT/NG-10

Kit Lot No.: 1001452762

Cartridge Lot No.: 42703

Kit Expiration Date: 2026 10 11

Legal Manufacturer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94809 USA

Manufacturing Facility
Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

○ Solna ○ Sunnyvale

◉ Lodi

Functional Testing according to D16904, Rev. AL.1

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 therefore valid without a wet signature

26 OCT 2024

Signature of Quality Assurance, **Date**

Name: Nhat Dao

Title: Quality Systems Specialist