

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.: 1001471323		
Cartridge Lot No.: 43309		
Kit Expiration Date: 2027-01-17		
Legal Manufacture Cepheid 904 Caribbean Drive Sunnyvale, CA 9480	Cepheid 121 N Guild Avenue) Solna Sunnyvale
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
Signature of Quality Name: Rose Ann D		a wet signature