

Quality Systems Specialist

Title:

## **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).

dian Medical Devices F	Regulations (CMDR).		
Product Name: Xpert	® CT/NG		
Cepheid Catalogue Pa	art No.: GXCT/NG-10		
Kit Lot No.: 1001456	5643		
Cartridge Lot No.: 42	2708		
Kit Expiration Date:	2026-10-25		
Legal Manufacturer Cepheid 904 Caribbean Drive Sunnyvale, CA 94809  Functional Testing a	Cepheid 121 N Guild Avenue	Solna C	Sunnyvale
Test Description	Acceptance Criteria	Test Result	
Positive	CT detected; NG detected	Passed	
Negative	CT not detected; NG not detected	Passed	
Signature of Quality Name: Julie Millet	cument is produced electronically and therefore valid without a 10 Nov 24  Assurance, Date	wet signature	