

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	Regulations (CMDR).	
Product Name: Xpe	rt® CT/NG	
Cepheid Catalogue I	Part No.: GXCT/NG-10	
Kit Lot No.: 100145	51816	
Cartridge Lot No.: 42605		
Kit Expiration Date:	2026-09-27	
Legal Manufacture Cepheid 904 Caribbean Drive Sunnyvale, CA 9480 Functional Testing	Cepheid 121 N Guild Avenue	) Solna Sunnyvale
Test Description	Acceptance Criteria	Test Result
Positive	CT detected; NG detected	Passed
Negative	CT not detected; NG not detected	Passed
If checked, this do  Signature of Quality  Name: Julie Millet		a wet signature