

Product Name: Xpert® CT/NG

Title: QA Analyst

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 Device Regulations (CMDR).

Cepheid Catalogue Part No.: GXCT/NG-CE-10		
Kit Lot No.: 1000272922		
Cartridge Lot No.: 32816		
Kit Expiration Date: 2023-06-18		
Legal Manufacturer Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden Functional Testing	Manufacturing Facility Solna Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden	Sunnyvale
Test Description	Acceptance Criteria	Test Result
Positive	CT detected; NG detected	Passed
Negative	CT not detected; NG not detected	Passed
5	20210709	
Signature of Quality Assurance Date		
Name: Siri Kierraren		