

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).

Product Name: Xpert® CT/NG		
Cepheid Catalogue Part No.: GXC	Γ/NG-CE-10	
Kit Lot No.: 1000214981		
Cartridge Lot No.: 32201		
Kit Expiration Date: 2022-08-14		
Legal Manufacturer	Manufacturing Facility	○ Sunnyvale
Cepheid AB	Cepheid AB	
Röntgenvägen 5	Röntgenvägen 5	
SE-17154 Solna	SE-171 54 Solna	
Sweden	Sweden	
Functional Testing		
Test Description	Acceptance Criteria	Test Result
Positive	CT detected; NG detected	Passed
Negative	CT not detected; NG not detected	Passed

Signature of Quality Assurance

Name: Siri Kjerrgren

Title: QA Analyst