

Product Name: Xpert® CT/NG

## **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.: 1000	271345			
Cartridge Lot No.: 32804				
Kit Expiration Date: 2023-06-11				
Legal Manufacturer Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden		Manufacturing Facility Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden	Solna ○	Sunnyvale
Functional Testing				
Test Description	Acceptance Criteria			Test Result
Positive	CT detected; NG detected			Passed
Negative	CT not detected; NG not detected			Passed
5 /- 20210625				
Signature of Quality Assurance Date				
Name: Siri Kjerrgren				
Title: QA Analyst				