

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.: GXCT/NG-CE-10			
Kit Lot No.: 100040	1727			
Cartridge Lot No.: 3371	8			
Kit Expiration Date: 202	24-04-21			
Legal Manufacturer		Manufacturing Facility	Solna	Sunnyvale
Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden		Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden		ŕ
Sweden				
Functional Testing				
Test Description	Acceptance Criteria		Test Result	
Positive	CT detected; NG detected			Passed
Negative	CT not detected; NG not detected			Passed

Water 20220509	
Signature of Quality Assurance	Date
Name: Wafa Qasim	
Title: QA Analyst	