

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.: G.	XCT/NG-CE-10			
Kit Lot No.: 1000146460				
Cartridge Lot No.:31304				
Kit Expiration Date: 2021-02-07				
Legal Manufacturer		Manufacturing Facility		← Sunnyvale
Cepheid AB Röntgenvägen 5 SE-17154 Solna				, , , , , , ,
Sweden				
Functional Testing				
Test Description	Acceptance Criteria		Test Result	
Positive	CT detected; NG detected		Passed	
Negative	CT not detected; NG not detected		Passed	

Muccliel	20190416
Signature of Quality Assurance	Date
Name: Samaneh Vahid	
Title: OA Analyst	