



## 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.: 1000133826

Cartridge Lot No.: 27202

Kit Expiration Date: 2020-09-27

Legal Manufacturer

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna  
Sweden

Manufacturing Facility

Solna

Sunnyvale

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

*Functional Testing*

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	CT detected; NG detected	Passed
Negative	CT not detected; NG not detected	Passed

  
Signature of Quality Assurance

Date

Name: Emaela S. Quan-Tong

Title: Quality Systems Specialist