



## 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<sup>®</sup> CT/NG

Cepheid Catalogue Part No.:

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid AB  
Röntgenvägen 5  
SE-17154 Solna  
Sweden

Manufacturing Facility

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

Solna     Sunnyvale

*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             |

30 SEP 2020

Signature of Quality Assurance

Date

Name:

Title: