



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.: 1000187638

Cartridge Lot No.: 31421

Kit Expiration Date: 2022-02-06

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

 2020 04 14
Signature of Quality Assurance Date

Name: Samaneh Vahid

Title: QA Analyst