Cepheid

# 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.: 1000232601

Cartridge Lot No.: 32225

Kit Expiration Date: 2022-11-20

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility (●) Solna ( ) Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

*Functional Testing*

| *Test Description* | *Acceptance Criteria* | *Test Result* |
|---|---|---|
| Positive | CT detected; NG detected | Passed |
| Negative | CT not detected; NG not detected | Passed |

RoFB 20201211

**Signature of Quality Assurance** **Date**

Name: Robert Fiedler

Title: QA Analyst