



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 Devices Regulations (CMDR).

Product Name: Xpert® TV

Cepheid Catalogue Part No.: GXTV-10

Kit Lot No.: 1001450728

Cartridge Lot No.: 22101

Kit Expiration Date: 2026 03 29

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA



Solna



Sunnyvale



Lodi

Functional Testing according to D20618, Rev. M

| <i>Test Description</i> | <i>Acceptance Criteria</i> | <i>Test Result</i> |
|-------------------------|----------------------------|--------------------|
| LOW Positive | TV detected | Passed |
| HIGH Positive | TV detected | Passed |
| Negative | TV not detected | Passed |

If checked, this document is produced electronically and therefore valid without a wet signature

Sarah Bagasol 16092024
Signature of Quality Assurance, Date

Name: Sarah Bagasol

Title: Quality Assurance Specialist