# 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® MTB/RIF Ultra

**Cepheid Catalogue Part No.:** GXMTB/RIF-ULTRA-50

**Kit Lot No.:** 1001421874

**Cartridge Lot No.:** 47904

**Kit Expiration Date:** 2025 09 28

**Legal Manufacturer**
Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

**Manufacturing Facility**
Cepheid
121 N Guild Avenue
Lodi, CA 95240
USA

○ Solna ○ Sunnyvale

◉ Lodi

***Functional Testing according to D25862, Rev.*** AN

| *Test Description* | *Acceptance Criteria* | *Test Result* |
|---|---|---|
| Wild Type Control | MTB DETECTED VERY LOW; Rif Resistance NOT DETECTED<br>or<br>MTB DETECTED LOW; Rif Resistance NOT DETECTED<br>or<br>MTB DETECTED MEDIUM; Rif Resistance NOT DETECTED<br>or<br>MTB DETECTED HIGH; Rif Resistance NOT DETECTED | Passed |
| Mutant Control | MTB DETECTED VERY LOW;RIF Resistance DETECTED<br>or<br>MTB DETECTED LOW;RIF Resistance DETECTED<br>or<br>MTB DETECTED MEDIUM;RIF Resistance DETECTED<br>or<br>MTB DETECTED HIGH;RIF Resistance DETECTED | Passed |
| Negative | MTB NOT DETECTED | Passed |

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

**Signature of Quality Assurance,** **Date** 10APR2024

**Name:** Laiza Guevarra

**Title:** Quality Systems Specialist