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 Devices Regulations (CMDR).

Product Name: Xpert® MTB/RIF Ultra

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

Kit Lot No.: 1001417594

Cartridge Lot No.: 47309

Kit Expiration Date: 2025 08 24

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 or MTB DETECTED LOW; Rif Resistance NOT DETECTED or MTB DETECTED MEDIUM; Rif Resistance NOT DETECTED or MTB DETECTED HIGH; Rif Resistance NOT DETECTED	Passed
Mutant Control	MTB DETECTED VERY LOW;RIF Resistance DETECTED or MTB DETECTED LOW;RIF Resistance DETECTED or MTB DETECTED MEDIUM;RIF Resistance DETECTED or 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

Sarah Bagasol — 10 MAR 2024

Signature of Quality Assurance, **Date**

Name: Sarah Bagasol

Title: Quality Assurance Specialist