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, the Canadian Medical Devices Regulations (CMDR), and the China National Medical Products Administration's Quality System Requirements.

Product Name: Xpert® MTB/RIF Ultra

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

Kit Lot No.: 1001448302

Cartridge Lot No.: 71219

Kit Expiration Date: 2026-03-15

Legal Manufacturer
Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility
Cepheid AB
Röntgenvägen 5
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(●) 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

Robert Fiedler
Robert Fiedler (Sep 26, 2024 14:25 GMT+2)

Signature of Quality Assurance, **Date**

Name: Robert Fiedler

Title: QA Analyst