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.: 1001448303

Cartridge Lot No.: 71611

Kit Expiration Date: 2026-03-15

Legal Manufacturer	**Manufacturing Facility**	
Cepheid AB Röntgenvägen 5 SE-17154 Solna Sweden	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden	● 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 27, 2024 12:35 GMT+2)

Signature of Quality Assurance,   **Date**

Name: Robert Fiedler

Title: QA Analyst