



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.: 1001452740

Cartridge Lot No.: 60604

Kit Expiration Date: 2026 04 12

Legal Manufacturer

Cepheid AB
 Röntgenvägen 5
 SE-17154 Solna
 Sweden

Manufacturing Facility

Cepheid
 121 N Guild Avenue
 Lodi, CA 95240
 USA

Solna

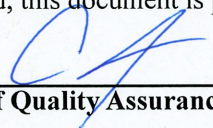
Sunnyvale

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


10/25/2024

 Signature of Quality Assurance, Date

Name: Crystal Sysenglath
Title: Quality Systems Specialist