

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.: 1001306552

Cartridge Lot No.: 46910

Kit Expiration Date: 2025-04-13

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. AM

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
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

Signature of Quality Assurance,  Date 30 OCT 2023

Name: Chong Moua

Title: Quality Systems Specialist I