



## 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.:** 1001223335

**Cartridge Lot No.:** 46312

**Kit Expiration Date:** 2025-03-09

**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<br>or<br>MTB DETECTED LOW; Rif Resistance NOT DETECTED<br>or<br>MTB DETECTED MEDIUM; Rif Resistance NOT DETECTED<br>or<br>MTB DETECTED HIGH; Rif Resistance NOT DETECTED | Passed             |
| Mutant Control          | MTB DETECTED VERY LOW; Rif Resistance DETECTED<br>or<br>MTB DETECTED LOW; Rif Resistance DETECTED<br>or<br>MTB DETECTED MEDIUM; Rif Resistance DETECTED<br>or<br>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,

9/28/2023  
\_\_\_\_\_  
Date

**Name:** Mai Kue

**Title:** Quality System Specialists