

## 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 India Medical Device Rules, ISO 13485, and European IVD Directive.

**Part No.:** GXMTB/RIF-ULTRA-50  
**Part Description:** XPERT MTB/RIF ULTRA,50-TEST KIT,CE-IVD  
**Batch No.:** 1001417593  
**Lot No.:** 47308  
**Expiration Date:** 2025-08-24

**Legal Manufacturer:**

Cepheid AB  
 Röntgenvägen 5  
 SE-171 54 Solna  
 Sweden

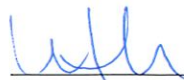
**Manufacturing Facility**

Cepheid India Private Limited  
 Plot No-37/2, Survey No 198, Block Nos-55,56,57,60 and 61  
 Hitech Defence and Aerospace Park Industrial area  
 Mahadevakodigehalli Village, Hobli Jala Taluka  
 Bengaluru (Bangalore) Urban, Karnataka (India) – 562149

*Functional Testing according to D25862, Rev: AN*

<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 valid without a wet signature.



Signature of Quality Assurance

Nancy Inthavisak

Name

Quality Systems Specialist

Title

2024-03-07

Date (YYYY-MM-DD)