

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.: GXI	MTB/RIF-ULTRA-50				
Kit Lot No.: 1001431893					
Cartridge Lot No.: 59102					
Kit Expiration Date: 2025-11-16					
Legal Manufacturer	Manufacturing Facility				
Cepheid AB	Cepheid AB		Solna		Sunnyvale
Röntgenvägen 5	Röntgenvägen 5				
SE-17154 Solna	SE-171 54 Solna	_			
Sweden	Sweden		Lodi		

Functional Testing according to D25862, Rev. AN

Title: QA Analyst

Test Description	Acceptance Criteria	Test Result	
Wild Type Control	MTB DETECTED HIGH, Rif Resistance NOT DETECTED MTB DETECTED VERY LOW, RIF Resistance DETECTED or MTB DETECTED LOW, BIF Resistance DETECTED.		
Mutant Control			
Negative	MTB NOT DETECTED	Passed	

	Negative	MTB NOT DETECTED	Passed					
	If checked, this document is produced electronically and therefore valid without a wet signature							
	Lol	2024-06-06						
/	Signature of Quality	Assurance, Date						
	Name: Alexander A	Avramidis						