

Quality Systems Specialist

Title:

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).

lian Medical Devices	Regulations (CMDR).		
Product Name: Xper	t® MTB/RIF Ultra		
Cepheid Catalogue P	art No.: GXMTB/RIF-ULTRA-50		
Kit Lot No.: 100134	1095		
Cartridge Lot No.: 4	7213		
Kit Expiration Date:	2025 05 04		
Legal Manufacture Cepheid AB Röntgenvägen 5 SE-17154 Solna	Cepheid 121 N Guild Avenue) Solna	Sunnyval
Sweden	Lodi, CA 95240 USA	Lodi	
Test Description	Acceptance Criteria	Test Result	7
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	
	ocument is produced electronically and therefore valid without a	a wet signature	-
Signature of Quant	Assurance, Date		
Name: Crystal Sys			