

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).

ian Medical Devices Regu	nations (CMDR).		
Product Name: Xpert® M	ITB/RIF Ultra		
Cepheid Catalogue Part I	No.: GXMTB/RIF-ULTRA-50		
Kit Lot No.: 1001440588	3		
Cartridge Lot No.: 6020	9		
Kit Expiration Date: 202	6-02-01		
egal Manufacturer	Manufacturing Facility		
Cepheid AB	Cepheid	Solna O	Sunnyv
Röntgenvägen 5	121 N Guild Avenue		
E-17154 Solna	Lodi, CA 95240		
	Dodi, 011 752 10		
weden	USA rding to D25862, Rev. AN	• Lodi	
weden	USA rding to D25862, Rev. AN Acceptance Criteria	Lodi Test Result	
weden Functional Testing acco	USA rding to D25862, Rev. AN		
weden Functional Testing acco Test Description	USA rding to D25862, Rev. AN Acceptance Criteria 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	Test Result	
Functional Testing accordance Test Description Wild Type Control	Acceptance Criteria Acceptance Criteria 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 or MTB DETECTED VERY LOW; RIF Resistance DETECTED or MTB DETECTED LOW; RIF Resistance DETECTED or MTB DETECTED LOW; RIF Resistance DETECTED or MTB DETECTED MTB DETE	Test Result Passed	
Functional Testing accordance Test Description Wild Type Control Mutant Control Negative	Acceptance Criteria 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 or MTB DETECTED HIGH; Rif Resistance DETECTED MTB DETECTED VERY LOW; RIF Resistance DETECTED or MTB DETECTED 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 OT MTB DETECTED HIGH; RIF Resistance DETECTED	Passed Passed Passed	
Functional Testing accordance Test Description Wild Type Control Mutant Control Negative	Acceptance Criteria 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 OR MTB DETECTED HIGH; Rif Resistance DETECTED OR MTB DETECTED LOW; RIF Resistance DETECTED OR MTB DETECTED LOW; RIF Resistance DETECTED OR MTB DETECTED MEDIUM; RIF Resistance DETECTED OR MTB DETECTED MEDIUM; RIF Resistance DETECTED OR MTB DETECTED HIGH; RIF Resistance DETECTED OR MTB DETECTED HIGH; RIF Resistance DETECTED MTB NOT DETECTED MTB NOT DETECTED PRODUCED RESISTANCE VALIDATION OF WHAT ALL AND	Passed Passed Passed	