Cepheid

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 Device Regulations (CMDR).

Product Name: Xpert® MTB/RIF Ultra

Cepheid Catalogue Part No.: GXMTB/RIF-ULTRA-10

Kit Lot No.: 1000153415

Cartridge Lot No.: 13510

Kit Expiration Date: 2020-04-19

Legal Manufacturer

Cepheid AB
Röntgenvägen 5
SE-17154 Solna
Sweden

Manufacturing Facility (•) Solna ( ) Sunnyvale

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Functional Testing

Test Description	*Acceptance Criteria*	*Test Result*
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

Kambiz Ghaderi 20190517

Signature of Quality Assurance **Date**

Name: Kambiz Ghaderi

Title: QA Analyst