



## 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/XDR**

Cepheid Catalogue Part No.: **GXMTB/XDR-10**

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid AB  
Röntgenvägen 5  
SE-17154 Solna  
Sweden

Manufacturing Facility

Solna

Sunnyvale

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089 USA

*Functional Testing*

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	MTB NOT DETECTED	Passed
Positive - Wild Type	MTB DETECTED;INH Resistance NOT DETECTED;FLQ Resistance NOT DETECTED;AMK Resistance NOT DETECTED;KAN Resistance NOT DETECTED;CAP Resistance NOT DETECTED;ETH Resistance NOT DETECTED	Passed
Positive - Mutant	MTB DETECTED;INH Resistance DETECTED;FLQ Resistance DETECTED;AMK Resistance DETECTED;KAN Resistance DETECTED;CAP Resistance DETECTED;ETH Resistance DETECTED	Passed

Tanja Reed

Tanja Reed (Dec 13, 2023 13:40 PST)

Dec 13, 2023

Signature of Quality Assurance

Date

Name:

Title:





# 1001308444

Final Audit Report

2023-12-13

Created:	2023-12-13
By:	Tanja Reed (tanja.reed@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAPPtVC-5JasBkOWVvPMYTL5PYO1rriwd

## "1001308444" History

-  Document created by Tanja Reed (tanja.reed@cepheid.com)  
2023-12-13 - 9:38:51 PM GMT
-  Document emailed to Tanja Reed (tanja.reed@cepheid.com) for signature  
2023-12-13 - 9:39:25 PM GMT
-  Document e-signed by Tanja Reed (tanja.reed@cepheid.com)  
Signature Date: 2023-12-13 - 9:40:03 PM GMT - Time Source: server
-  Agreement completed.  
2023-12-13 - 9:40:03 PM GMT