



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® MRSA

Cepheid Catalogue Part No.:

Kit Lot No.:

Cartridge Lot No.:

Kit Expiration Date:

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

- Solna
- Sunnyvale
- Lodi

Functional Testing according to D16895, Rev. AA

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Positive	MRSA Positive	Passed
Negative	MRSA Negative	Passed

If checked, this document is produced electronically and therefore valid without a wet signature

ThuyTien Nguyen
ThuyTien Nguyen (Mar 14, 2024 10:40 PDT)

Mar 14, 2024

Signature of Quality Assurance, _____ **Date**

Name: ThuyTien Nguyen

Title: Quality Systems Specialist





1001420191

Final Audit Report

2024-03-14

Created:	2024-03-14
By:	ThuyTien Nguyen (thuytien.nguyen@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABA6K6YpaNbJmU-M5hn-G9VxTAwmc0qBRoWI

"1001420191" History

-  Document created by ThuyTien Nguyen (thuytien.nguyen@cepheid.com)
2024-03-14 - 5:39:21 PM GMT
-  Document emailed to ThuyTien Nguyen (thuytien.nguyen@cepheid.com) for signature
2024-03-14 - 5:39:49 PM GMT
-  Document e-signed by ThuyTien Nguyen (thuytien.nguyen@cepheid.com)
Signature Date: 2024-03-14 - 5:40:11 PM GMT - Time Source: server
-  Agreement completed.
2024-03-14 - 5:40:11 PM GMT