

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.

Product Name: Xpert® NPM1 Mutation

Cepheid Catalog Part No.: RNPM1-10

Kit Lot No.: 1001457084

Cartridge Lot No.: 03001

Kit Expiration Date: 2025-06-29

Legal Manufacturer

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Solna Sunnyvale Newark Lodi

Functional Testing

<i>Test Description</i>	<i>Acceptance Criteria</i>	<i>Test Result</i>
Negative	NPM1 NOT DETECTED [Sufficient ABL Transcript]	Passed
~.2% (NPM1/ABL)	NPM1 Mutation DETECTED	Passed
~ 1% (NPM1/ABL)	NPM1 Mutation DETECTED	Passed

ThuyTien Nguyen
ThuyTien Nguyen (Nov 15, 2024 11:03 PST)

Nov 15, 2024

Signature of Quality Assurance,

Date

Name: ThuyTien Nguyen

Title: Quality Systems Specialist





RNPM1-10 1001457084

Final Audit Report

2024-11-15

Created:	2024-11-15
By:	ThuyTien Nguyen (thuytien.nguyen@cepheid.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAgrqNNIHv8Kp-7StdDTPr82Jx2Jmzub

"RNPM1-10 1001457084" History

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2024-11-15 - 7:00:52 PM GMT- IP address: 45.62.187.22
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2024-11-15 - 7:03:09 PM GMT
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Signature Date: 2024-11-15 - 7:03:19 PM GMT - Time Source: server- IP address: 45.62.187.22
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