

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 Devices Regulations.

Product Name: Xpert® NPM1 Mutation
Cepheid Catalog Part No.: GXNPM1-CE-10
Kit Lot No.: 1001471161
Cartridge Lot No.: 03201
Kit Expiration Date: 2025-07-27

Legal Manufacturer

Cepheid
 904 Caribbean Drive
 Sunnyvale, CA 94089 USA

Manufacturing Facility

Cepheid
 904 Caribbean Drive
 Sunnyvale, CA 94089
 USA



Solna



Sunnyvale



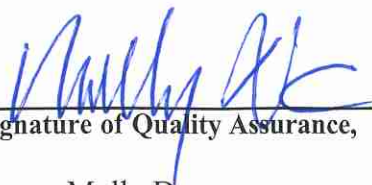
Newark



Lodi

Functional Testing

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



 Signature of Quality Assurance,



 Date

Name: Molly Doan

Title: Quality Systems Specialist