



# Xpert® NPM1 Mutation

## Datasheet — CE-IVD

<b>Test Reagent Kit</b>	Xpert NPM1 Mutation
<b>Catalog Number</b>	GXNPM1-CE-10
<b>Technology</b>	Nested RT-qPCR
<b>Indication</b>	Quantification of mutant NPM1 mRNA transcripts (types A, B, and D in exon 12)
<b>Batch or On-Demand</b>	On-Demand
<b>Reagents on Board</b>	Yes, excluding some sample preparation
<b>Minimum Run Size</b>	1
<b>Sample Extraction</b>	Partially automated in cartridge
<b>Precision Pipetting Required</b>	Yes (Lysate preparation)
<b>Total Time to Result</b>	≤3 hours
<b>Test Run Time</b>	≤2.5 hours
<b>Off-board Sample Preparation Time</b>	≤30 minutes
<b>Internal Controls</b>	
<b>Endogenous Control</b>	Yes (ABL1)
<b>Probe Check Control (PCC)</b>	Yes
<b>Software Required</b>	GeneXpert Dx software v6.2 or higher
<b>Sensitivity (EDTA)</b>	0.030%
<b>Linear Range</b>	500% – 0.030% NPM1 Mutation/ABL1
<b>Sample Required</b>	Peripheral blood (EDTA whole blood)
<b>Sample Volume Required</b>	4 mL
<b>Sample Stability</b>	2–8 °C for up to 72 hours
<b>Sample Tested in Xpert Cartridge</b>	Lysate (quantity sufficient for 3 tests)
<b>Kit Storage</b>	2–8 °C
<b>Commercial Controls</b>	Yes, available via independent 3rd party. Contact Technical Support (Email: techsupport@cepheid.com)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not available in all countries. Not available in the United States.

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