



Xpert[®] NPM1 Mutation

Datasheet — CE-IVD

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