



# Xpert<sup>®</sup> NPM1 Mutation

## Datasheet — For Research Only (RUO)

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| <b>Assay Reagent Kit</b>   | Xpert NPM1 Mutation  |
| <b>Catalog Number</b>  | RNPM1-10   |
| <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>Assay Run Time</b>  | <2.5 hours   |
| <b>Off-board Sample Preparation Time</b>                         | <30 minutes  |
| <b>Internal Controls</b>   | Yes  |
| <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/ABL  |
| <b>Sample Required</b>   | Peripheral blood (EDTA)  |
| <b>Sample Volume Required</b>                                    | 4 mL   |
| <b>Sample Stability</b>  | 2–8 °C up to 72 hours  |
| <b>Sample Tested in Xpert Cartridge</b>                          | Lysate (quantity sufficient for 3 tests)                                     |
| <b>Alignment to IVT-RNA copy numbers using Primary Standards</b> | Yes, with every lot  |
| <b>Kit Storage</b>   | 2–8 °C   |
| <b>Commercial Controls</b>                                       | Yes, available via independent 3rd party<br>Contact Technical Support        |

For Research Use Only. Not for use in diagnostic procedures. Not reviewed by any regulatory body.

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