



For Research Use Only (RUO)

■ Xpert® NPM1 Mutation Assay



For research use only. Not for use in diagnostic procedures.



## The Need

Current testing options for NPM1 are not only cumbersome, but also expensive and time consuming for the lab to implement because:

- Available testing methods are complex and create inefficient laboratory workflows.
- No international scale has been established for NPM1 monitoring, so laboratories are dependent on ratios and must run laborious standard curves.



## The Solution

Leveraging Cepheid's **Lab in a Cartridge™** technology, the Xpert® NPM1 Mutation assay decreases workflow complexity and hands-on time by automating the entire testing process, delivering faster results.

The Xpert NPM1 Mutation assay is a quantitative assay for the NPM1 mutation transcripts (types A,B and D in exon 12) as a ratio of NPM1 Mutation/ABL1. It provides high assay sensitivity, standardization, and on-demand molecular results in about 3 hours. With minimal hands-on time and a streamlined workflow, the Xpert NPM1 Mutation assay eliminates the need for time consuming hands-on processes and enables researchers to run NPM1 testing in-house.

### Easy to Use

- < 3 hours total testing process
- Simply add treated blood sample and an off-board reagent to the Xpert test cartridge

### Robust Design

- Includes two internal controls
- 4 mL input volume of whole blood supports high assay sensitivity for detection of low-level transcripts

Coverage, plus  
Accuracy, plus  
Peace of mind

That's the PCR<sup>plus</sup> advantage.  
From Cepheid.



## The Impact

- **Clinical Researcher:** Same day information
- **Laboratory:** Flexibility and simplicity for a more streamlined workflow

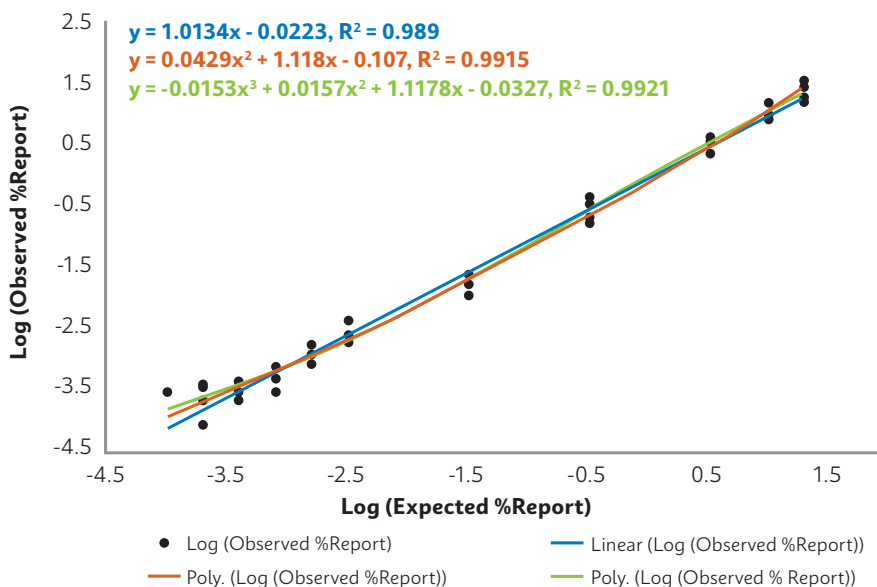
### Move your lab forward

- **Decrease costs:** Eliminate need for standard curve and replicate testing
- **Optimize lab organization:** Free up technician time for other lab activities
- **Provide flexibility:** Process any number of samples, any day of the week, with a fixed cost per sample
- **Simplify reporting:** Deliver information on concise one-page report

## Technical Performance

Linearity was evaluated independently for each of the three subtypes, mutA, mutB and mutD, using cell lysates that were specific for a high level of either the mutA, mutB or mutD subtype. Lysate from each high level of NPM1 mutation cell line was diluted in a background lysate prepared from AML-negative sample to target ranges of ~2000% to 0.01% NPM1 Mutation/ABL. The panel members, including the negative level, were tested on one assay kit lot in replicates of 4. Testing and statistical analyses were conducted in accordance with CLSI EP06-A. Linear regression analyses were performed for first, second and third order polynomials. The results for each subtype were considered linear if the polynomial regression coefficients were insignificant (p-values > 0.05). If p-values for the polynomial regression coefficients are < 0.05, then the maximum absolute difference at any level between higher order and linear predictions should be < 0.3 LR (corresponding to a 2-fold difference).

### Linear Regression Curves for Subtype Transcript mutA



## Workflow: 3 Easy Steps

1

Transfer the wash reagent into chamber



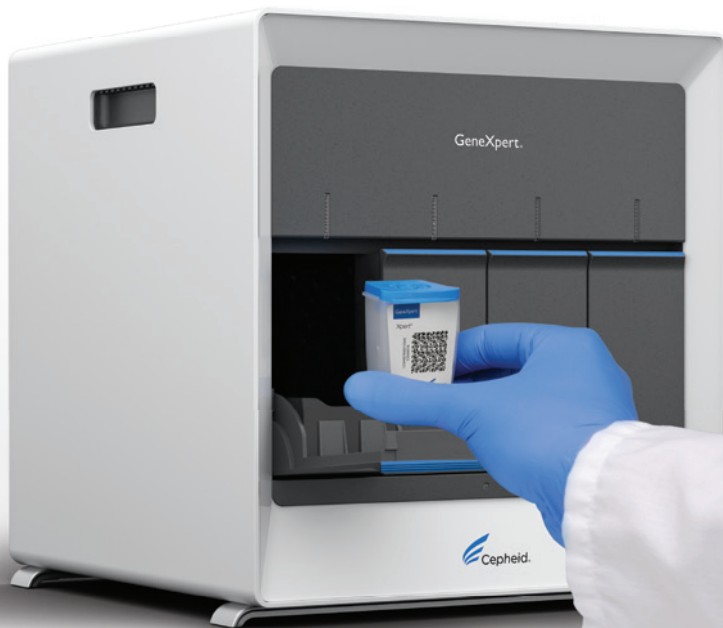
2

Pipette entire contents of prepared sample (~4.5mL) into the sample chamber



3

Insert cartridge and start test



## Catalog Information

Xpert® NPM1 Mutation Assay

10 tests

RNPM1-10

### References:

Xpert NPM1 Mutation RUO IFU ENGLISH 302-5822 Rev. B

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