

# Xpert® NPM1 Mutation

*For sensitive, fast, and on-demand monitoring of NPM1 mRNA transcripts in AML patients*

## The Facts

Acute myeloid leukemia (AML) is a heterogeneous disorder characterized by clonal expansion differentiation, and uncontrolled proliferation of myeloid progenitors (blasts) in peripheral blood and bone marrow.<sup>1,2</sup> It is the most common acute leukemia in adults and is known to have various Nucleophosmin (NPM1) exon 12 mutations.<sup>1</sup>

The NPM1 is one of the most common genetic abnormalities in AML, accounting for about 30% to 35% of cases.<sup>3,4</sup> The WHO identified NPM1 mutated AML as a distinct entity in 2017.<sup>3</sup> The determination of NPM1 mutation status has become essential for the molecular classification of AML. Established international organizations recommend definitive timepoints for monitoring NPM1 in AML patients.<sup>5,6</sup>



Across European countries, **the incidence is 3.5 cases per 100,000 population per year and the five-year survival is 17.5% approximately.**<sup>1,7</sup>



AML represents about **80% of acute leukemia in adults, with a median age at diagnosis of 67-68 years.**<sup>1,7,8</sup>



**No International Standards** for quantitation of the NPM1 mutation transcript for AML.

## Xpert NPM1 Mutation

### Effectiveness for your patients

Xpert NPM1 Mutation is an automated test for quantifying the amount of mutant NPM1 mRNA transcripts (types A, B, and D in exon 12) as a ratio of NPM1 Mutation/ABL1 with high sensitivity. The test is performed on the innovative GeneXpert® technology, which automates and integrates sample purification, nucleic acid amplification, and target sequence detection in simple or complex samples using real-time RTPCR and nested PCR assays in one automated cartridge.\*



**Dynamic range\***  
500% to 0.030% NPM1 Mutation/ABL1



**Standardized results**  
Proprietary in-house RNA control materials in every lot



**Time to result\***  
≤3 hours

## Your needs

### Make the right decisions



## Our answers

Facilitating the decision making process at critical moments thanks to the sensitivity and quality of the test:

#### The test sensitivity meets clinical requirements:

- Dynamic range between between 500% to 0.030% NPM1 Mutation/ABL1\*
- Clinically demonstrated limit of detection (LoD) of 0.030%\*

### Improve patient's journey



The possibility of providing a **result in less than 3 hours following sample reception\*** allows the early prediction of a relapse **to be quickly identified and monitor the treatment and care effectiveness.**

### Answer patient's needs



Relapse remains the most common cause of treatment failure for AML patients.<sup>9</sup> **Timely monitoring ensures measurement of treatment response and detection of potential relapse.**<sup>10</sup>

### Strengthen ease of access to monitoring



Thanks to an easy-to-use test integrated in a fully automated process (on demand or in series), 2 internal controls integrated into each cartridge, and standardized reports,<sup>\*</sup> **results can be obtained and communicated to the patient under the same conditions and time, regardless of the setting where the test is performed.**



## What are the recommendations?

- Methods with high clinical sensitivity and specificity adapted to the molecular laboratory workflow are required for the diagnosis, prognosis, and monitoring of AML.<sup>10</sup>
- **European LeukemiaNet recommends to perform baseline molecular assessment by quantitative polymerase chain reaction (qPCR) or droplet digital PCR (dPCR) to understand response to initial therapy, and facilitate MRD monitoring after treatment for patients with mutant NPM1 and core-binding factor (CBF)-AML.**<sup>11</sup>

\* Instructions for use of the Xpert NPM1 Mutation (302-8304)

#### References:

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The Xpert® NPM1 Mutation test is a molecular biology test that is used on GeneXpert® systems. Manufacturer: Cepheid. Distributor: Cepheid Europe SAS.

Carefully read the instructions on the label and/or in the instructions for use. 01/2023

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries.

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