Cepheid
A better way.

Xpert® NPM1 Mutation

Fast, sensitive on-demand monitoring of NPM1 mutant mRNA transcripts in Acute Myeloid Leukemia patients

The Need

Acute Myeloid Leukemia (AML) is the most common acute leukemia in adults.[1] The Nucleophosmin (NPM1) mutation is one of the most common genetic abnormalities in AML, accounting for about 30% of cases.[2,3]

Established international organizations recommend periodic molecular assessment by quantitative PCR for monitoring NPM1 mutations in AML patients.[4-6]

No international scale is established for the quantification of the NPM1 mutant transcript for AML monitoring posing a challenge for quantitative monitoring.

The Solution

The **Xpert NPM1 Mutation** test 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.[7]

Proprietary in-house RNA control materials are used to calibrate and standardize each lot of the Xpert NPM1 Mutation.[8]

The Impact

- Timely monitoring ensures measurement of treatment response and detection of potential relapse.[6]
- Quickly classify AML subtype (NPM1-mutant vs NPM1 wild type) to guide clinical decisions and prognosis.[4]
- Minimize challenges associated with result interpretation with a fast, easy-to-use, on-demand test and standardized reports.[8]

1 Bocchia M, Carella AM, Mulè A, Rizzo L, Turrini M, Abbenante MC, Cairoli R, Calafiore V, Defina M, Gardellini A, Luzi G, Patti C, Pinazzi MB, Riva M, Rossi G, Sammartano V, Rigacci L. Therapeutic Management of Patients with FLT3 + Acute Myeloid Leukemia: Case Reports and Focus on Gilteritinib Monotherapy. Pharmgenomics Pers Med. 2022 Apr 22;15:393-407. doi: 10.2147/PGPM.S346688. PMID: 35496349; PMCID: PMC9041600.

2 Falini, B., Sciabolacci, S., Falini, L. et al. Diagnostic and therapeutic pitfalls in NPM1-mutated AML: notes from the field. Leukemia 35, 3113–3126 (2021). https://doi.org/10.1038/s41375-021-01222-4. NCCN. Clinical Practice Guidelines in Oncology; Chronic Myelogenous Leukemia (Access Version 2.2024, December 2023).

3 Kunchala P, Kuravi S, Jensen R, McGuirk J, Balusu R. When the good go bad: Mutant NPM1 in acute myeloid leukemia. Blood Rev. 2018; 32(3): 167-183. doi:10.1016/j.blre.2017.11.001.

4 Heuser M, Ofran Y, Boissel N, Brunet Mauri S, Craddock C, Janssen J, Wierzbowska A, Buske C. Acute myeloid leukemia in adult patients: ESMO Clinical Oractice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology, Special Article, Vol. 31, Issue 6, June 2020, Pages 697-712. doi: https://doi.org/10.1016/j.annonc.2020.02.018.

5 National Comprehensive Cancer Network. NCCN Guidelines for Patients – Acute Myeloid Leukemia, 2022. https://www.nccn.org/patients/guidelines/content/PDF/aml-patient.pdf. Accessed on January 11, 2023.

6 Döhner H, Wei AH, Appelbaum FR, Craddock C, DiNardo CD, Dombret H, Ebert BL, Fenaux P, Godley LA, Hasserjian RP, Larson RA, Levine RL, Miyazaki Y, Niederwieser D, Ossenkoppele G, Röllig C, Sierra J, Stein EM, Tallman MS, Tien HF, Wang J, Wierzbowska A, Löwenberg B. Diagnosis and management of AML in adults: 2022 recommendations from an international expert panel on behalf of the ELN. Blood. 2022 Sep 22;140(12):1345-1377. doi: 10.1182/blood.2022016867. PMID: 35797463.

7 Xpert NPM1 Mutation Instructions for Use

8 Liu Y, Kao M, Saatian B, Kayhan S, Zhao Y, Aslam A, Shridhar K, Yuan L. PB1775: DEVELOPMENT OF ASSAY CALIBRATION MEHTHODOLOGY FOR CEPHEID XPERT® NPM1 MUTATION PROTOTYPE ASSAY. Hemasphere. 2022 Jun 23;6(Suppl):1655-1656. doi: 10.1097/01.HS9.0000849952.50330.40. PMCID: PMC9429332.

Xpert® NPM1 Mutation

Product Reference Sheet — CE-IVD

Test Reagent Kit	Xpert NPM1 Mutation
Catalog Number	**CE-IVD** GXNPM1-CE-10
Technology	Nested RT-qPCR
Targets	Quantification of mutant NPM1 mRNA transcripts (types A, B, and D in exon 12)
Batch or On-Demand	On-demand
Minimum Batch Size	1
Sample Type	Peripheral blood (EDTA)
Sample Volume	4 ml
Sample Extraction	Automated/integrated
Precision Pipetting	Not Required
Off-board Sample Preparation Time	Approximately 30 minutes
TAT	Approximately 3 hours
Internal Controls	**Endogenous control (ABL1)** ✓ **Probe Check Control (PCC)** ✓
Sensitivity (EDTA)	0.030%
Linear Range	0.030%–500% NPM1 Mutation/ABL
System & Software	**GeneXpert Dx System** GeneXpert Dx software version 6.2 or higher
Sample Stability	2–8 °C for up to 72 hours
Kit Storage	2–8 °C
Commercial Controls	Refer to Instructions for Use (IFU) or Contact Cepheid Technical Support

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

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