sysmex | Lighting the way with diagnostics

Plasma-Safe-SeqS

AML-SEQ™

CLIA-validated ultra-sensitive liquid biopsy service to detect mutations of the three most prevalent genes found in Acute Myeloid Leukemia (AML) – IDH1/2 & NPM1

www.sysmex-inostics.com

Dedicated partner in the fight against AML

AML-SEQ™ rounds out the company's AML CLIA lab offerings. The broader AML-MRD-SEQ panel launched in October 2021. AML-MRD-SEQ is a more extensive panel for the detection of measureable residual disease (MRD) in 68 regions across 20 genes including the clinically established IDH1/2 and NPM1.

According to the National Cancer Institute (NCI), an estimated 20,050 new AML cases will be diagnosed in the United States in 2022.[1]

> *"We envision investigators and eventually physicians using AML-SEQ and AML-MRD-SEQ as a one-two-punch in the fight against AML and AML MRD. We are committed to developing tools to support the fight against this devastating disease. We must support management of patients suffering from AML by providing the accurate and sensitive detection of AML biomarkers."*
>
> Shinichi Sato, CEO of Sysmex Inostics, Inc.

In 2022, to accelerate treatments and testing for AML MRD, Sysmex joined the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium's (BC) four-year project to validate new methods of MRD detection and quantification as a measure of response and trial endpoints in AML.

Specifications

AML-SEQ demonstrates ultra-sensitive detection of low frequency mutations, with a calling threshold of 10 MM (0.05% MAF for 20,000 GE DNA input), while specificity remains very high.[2]

Genes	Gene regions	Clinical relevance
IDH1	127-135, 256-281	Established therapeutic indications, monitored for reduction/clearance
IDH2	135-154, 171-178, 310-322	
NPM1	260-275, 283-290	Established clinical validity for MRD

To learn more about the expanded AML-MRD-SEQ service, visit: https://sysmex-inostics.com/panels/aml-mrd-seq/

For more information about the FNIH AML-MRD Consortium, visit: https://www.fnih.org/what-we-do/programs/biomarkers-consortium-measurable-residual-disease-acute-myeloid-leukemia-mrd

REFERENCES

1 https://seer.cancer.gov/statfacts/html/amyl.html

2 Internal validation data on file, Sysmex Inostics 2022

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