ACUTE MYELOID LEUKEMIA DIAGNOSTICS

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BIOTYPE

ACUTE MYELOID LEUKEMIA

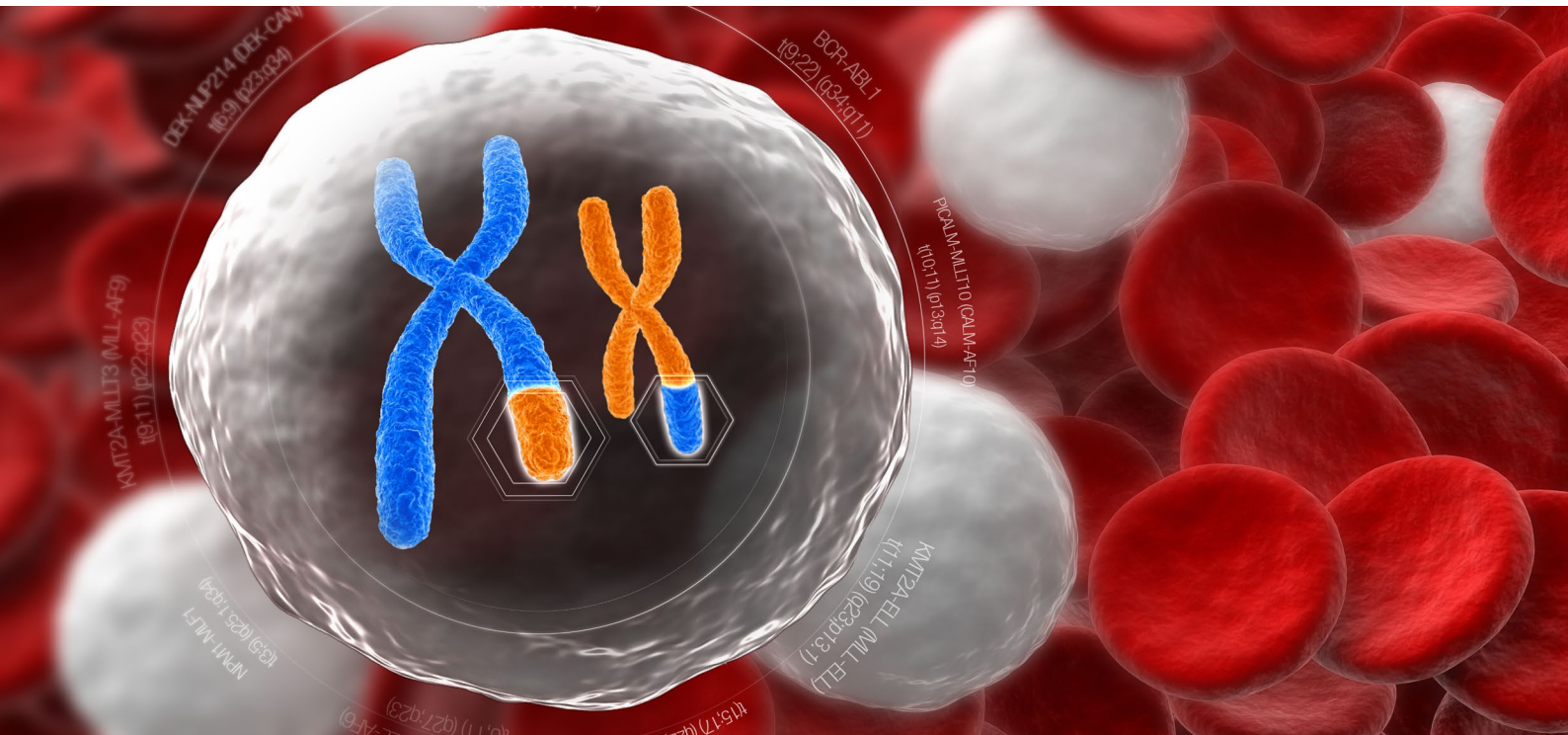
MOLECULAR-BASED AML DIAGNOSIS, CLASSIFICATION AND PROGNOSIS

Acute Myeloid Leukemia (AML) is a kind of malignant neoplasm of the hematopoietic system. This disease is characterized by an increase in myeloid cells in the bone marrow, resulting in hematopoiesis insufficiencies. An untreated AML will lead to a rapid disease progress and is fatal within weeks or months. Consequently, a quick and precise AML diagnosis is of utmost importance.

The examination of genetic aberrations supports the diagnosis of AML and complements the detection of an increased number of myeloid cells in peripheral blood or bone marrow. In this context, gene fusions generated from chromosomal translocations play an important role in the risk classification and prognosis of AML. Furthermore, AML with defined translocations, such as t(8;21) or t(9;2), has been specified as one's own entity and included in the WHO classification 2016[1].

REFERENCES

1 Arber DA, Orazi A, Hasserjian R et al.: The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. Blood 127:2391-2405, 2016. DOI:10.1182/blood-2016-03-643544



MULTIPLEX ANALYSIS

SUPPORT AML DIAGNOSIS WITH A SINGLE REACTION, MULTI-GENE FUSION SCREENING ASSAY

Biotype developed the Mentype® **AMLplex**QS assay to support clinicians in the diagnosis of AML. The assay comprises 11 gene fusions that allow the screening of 34 transcript variants concurrently in a single reaction. Hence, the assay aids in the assessment of favorable or unfavorable prognosis following the ELN guidelines of 2017[1].

Gene Fusion	Chromosomal Abberation	Transcript Variant	Prognosis According to ELN guidelines[1]
RUNX1-RUNX1T1	t(8;21) (q22:q22)	-	Favorable[1,2]
BCR-ABL	t(9;2) (q34;q11)	e1a3 e1a2 e14a2 (b3a2) e14a3 (b3a3) e13a2 (b2a2) e13a3 (b2a3)	Adverse[1]
PICALM-MLLT10	t(10;11) (p13;q14)	MLL10_240-PICALM_1987 MLL10_240-PICALM_2092	
CBFB-MYH11	inv(16) (p13;q22)	Type A/Type B/Type C/ Type D/Type E/Type F Type G/Type H/Type I Type J	Favorable[1,2]
DEK-NUP214	t(6;9) (p23;q34)	-	Adverse[1]*
KMT2A-MLLT4	t(6;11) (q27;q23)	-	Adverse[1]*
KMT2A-MLLT3	t(9;11) (p22;q23)	6A_(THP-1) 7A_(10A) 8A_(MM6) 6B_(9B)	Intermediate[1]
KMT2A-ELL	t(11;19) (q23;p13.1)	e10e2 e10e3	Adverse[1]
KMT2A-PTD	Partial Tandem Duplication	e9e3 e10e3 e11e3	Adverse[1]
NPM1-MLF1	t(3;5) (q25.1;q34)	-	
PML-RARA	t(15;17) (q22;q21)	bcr1 bcr2 bcr3	Favorable[2]*

* Prognosis dependend on additional genetic abnormalities

REFERENCES

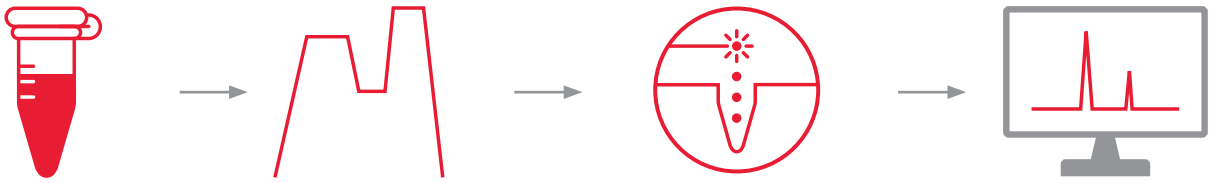
1 H. Döhner et al., „Diagnosis and management of AML in adults: 2017 ELN recommendations from an international expert panel", Blood, vol. 129, pp. 424-447, 2017.

2 S. Schnittger et al., „New score predicting for prognosis in PML-RARA, AML1-ETO, or CBFB-MYH11 acute myeloid leukemia based on quantification of fusion transcripts", Blood, vol. 102, pp 2746-2755, 2003.

Mentype® **AMLplex**QS

ENHANCE LABORATORY EFFICIENCY WITH A STREAMLINED WORKFLOW

Mentype® **AMLplex**QS is the comprehensive multiplex approach for a fast screening of AML driving gene fusions. The assay helps reduce hands-on time to a minimum by detecting all gene fusions in a single reaction, while conventional qPCR approaches commonly detect single gene fusions. Hence, starting from cDNA, the analysis of all covered transcript variants is completed in 3h.



AMLplex setup	**PCR amplification**	**Capillary gel electrophoresis**	**Data analysis**
15 min	110 min	45 min	10 min

3 hrs

ADDITIONAL ADVANTAGES

Clinical Performance

99.5% diagnostic specificity
94% diagnostic sensitivity

Broad Application

Compatible with all major ABI genetic analyzer

Data Analysis

Takes minutes through intuitive evaluation of electropherograms

YOUR BENEFITS

PRECISE AND ACCURATE DETECTION OF CHROMOSOMAL TRANSLOCATIONS

The Mentype® **AMLplex**^{QS} assay provides fast and reliable information on the presence of relevant gene fusions.

APPROVED FOR IN VITRO DIAGNOSTICS

Mentype® **AMLplex**^{QS} is registered as CE-IVD. Hence, the assay was validated in a clinical study and demonstrated its value to aid the diagnosis of AML.

ACCOMPLISH REQUIREMENTS

For the diagnosis of AML, the updated ELN[1] and WHO[2] guidelines require the detection of gene fusion transcripts. With Mentype® **AMLplex**^{QS}, clinicians and laboratories are following those guidelines.

COMPREHENSIVE CONTROL CONCEPT

The Mentype® **AMLplex**^{QS} is endowed with a comprehensive control concept. It comprises of internal controls to prove the template suitability and PCR integrity as well as of external positive and negative controls.

REFERENCES

1 H. Döhner et al., „Diagnosis and management of AML in adults: 2017 ELN recommendations from an international expert panel", Blood, vol. 129, pp. 424-447, 2017.
2 D. A. Arber et al., „The 2016 revision to the World Health Organization classification of myeloid neopalsms and acute leukemia", Blood, vol. 127, pp. 2391-2405, 2016.

ORDER INFORMATION

Product	Size	Cat. no.	Application
Mentype® **AMLplex**^{QS}	25	45-31220-0025	CE-IVD
	100	45-31220-0100	CE-IVD
	400	45-31220-0400	CE-IVD

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