Mentype® **AMLplex**QS CE IVD

Discover the course of acute myeloid leukaemia

Bio type® Diagnostic GmbH

Mentype® **AMLplex**QS is a cDNA-based multiplex-PCR analysis designed for subtype differentiation and diagnosis of acute myeloid leukaemia (AML). The assay identifies 11 fusion gene transcripts and 34 transcript variants in a single PCR amplification. As the ideal screening tool for fast, routine-fit and reliable diagnostics Mentype® **AMLplex**QS covers a wide range of therapy-relevant chromosomal aberrations (see table below). The test is performed by fragment length analysis using capillary gel electrophoresis as read out.

Mentype® **AMLplex**QS mediates highest specificity, is well established, and, routinely used in AML-diagnostics. Robust performance is guaranteed irrespective of the amount of cDNA applied. Due to the multiplex-format, Mentype® **AMLplex**QS streamlines, time-wise and economical, the diagnostic procedure by allowing high throughput screening (HTS) when compared to singleplex-PCR approaches. It represents the intelligent, efficient and reliable solution to screen chromosomal aberrations observed in AML-disease.

Chromosomal aberrations and variants of acute myeloid leukemia (AML) detected

Gen-fusions	Chromosomal aberrations	Variants
RUNX1-RUNX1T1 (AML1-ETO)	t(8;21) (q22;q22)	-
BCR-ABL1	t(9;22) (q34;q11)	e1a3
		e1a2
		e14a2 (b3a2)
		e14a3 (b3a3)
		e13a2 (b2a2)
		e13a3 (b2a3)
PICALM-MLLT10 (CALM-AF10)	t(10;11) (p13;q14)	MLLT10_240-PICALM_1987
		MLLT10_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
DEK-NUP214 (DEK-CAN)	t(6;9) (p23;q34)	-
KMT2A-MLLT4 (MLL-AF6)	t(6;11) (q27;q23)	-
KMT2A-MLLT3 (MLL-AF9)	t(9;11) (p22;q23)	6A_(THP-1)
		7A_(10A)
		8A_(MM6)
		6B_(9B)
KMT2A-ELL (MLL-ELL)	t(11;19) (q23;p13.1)	e10e2
		e10e3
KMT2A-PTD (MLL-PTD)	Partial Tandem Duplication	e9e3
		e10e3
		e11e3
NPM1-MLF1	t(3;5) (q25.1;q34)	-
PML-RARA	t(15;17) (q22;q21)	bcr1 (PR-L)
		bcr2 (PR-V)
		bcr3 (PR-S)

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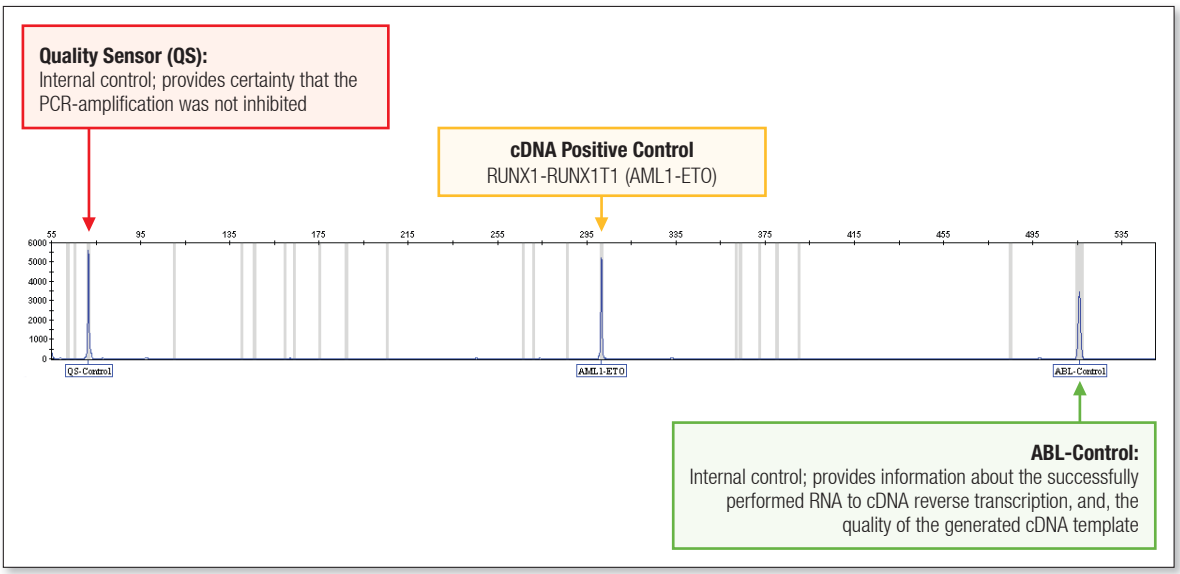
Mentype® **AMLplex**QS secures obtained result by two internal controls that do not require extra reagents. A Quality Sensor (QS) provides certainty that the PCR-amplification was not inhibited. The ABL-control provides information about the successfully performed RNA to cDNA reverse transcription, and, the quality of the generated cDNA template. Additionally, Mentype® **AMLplex**QS comes with RUNX1-RUNX1T1 (AML1-ETO) cDNA that might be applied as positive control. A triple-fold safeguard of obtained results together with accurate performance and clear read out enforces decision making.

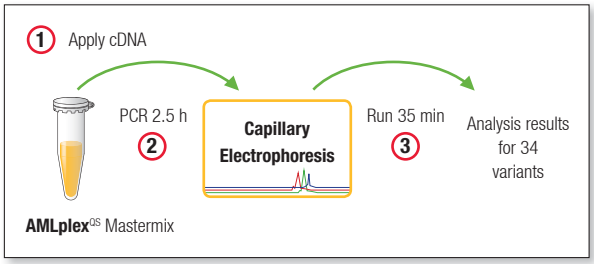
Fundamental profiling is vital for a fast therapeutic onset



Electropherogram of the Mentype® **AMLplex**QS control-setup using 500 ng of RUNX1-RUNX1T1 (AML1-ETO) cDNA. Analysis performed on an ABI PRISM® 3130 Genetic Analyzer with the DNA Size Standard 550 (BTO) using the GeneMapper® ID Software.

When to apply:

Mentype® **AMLplex**QS is ideally suited to stratify patient cohorts for study purposes and optimally completes cytogenetic approaches to initially diagnose AML. Due to its multiplex design it advances the laboratory routine by increasing efficiency and reducing costs. It therefore likewise optimally suits for laboratory control purposes.



Technical specifications

Optimal amount of template cDNA per reaction:
0.2 - 1.0 µg
Volume per PCR reaction: 25 µL
Fluorescence labels: 6-FAM™, BTG, BTY, BTO

Use with ABI PRISM® Genetic Analyzers

ABI PRISM® 310
ABI PRISM® 3130/3130xl/3500/3500xl
ABI PRISM® 3100-Avant/3100
ABI PRISM® 3700/3730

Ordering information

Mentype® **AMLplex**QS	Order number
10 reactions	45-31220-0010
25 reactions	45-31220-0025
100 reactions	45-31220-0100

Bio type® Diagnostic GmbH

Moritzburger Weg 67
D-01109 Dresden
Tel.: +49 351 8838 400
Fax: +49 351 8838 403
info@biotype.de
www.biotype.de