Mentype[®] **AMLplex**^{QS} **C€ IVD**

Discover the course of acute myeloid leukaemia

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
AML1-ETO	t(8;21) (q22;q22)	-
BCR-ABL	t(9;22) (q34;q11)	e1a3
		e1a2
		b3a2
		b3a3
		b2a2
		b2a3
CALM-AF10	t(10;11) (p13;q14)	AF10_240-CALM_1987
		AF10_240-CALM_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-CAN	t(6;9) (p23;q34)	-
MLL-AF6	t(6;11) (q27;q23)	-
MLL-AF9	t(9;11) (p22;q23)	6A_(THP-1)
		7A_(10A)
		8A_(MM6)
		6B_(9B)
MLL-ELL	t(11;19) (q23;p13.1)	e10e2
		e10e3
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)





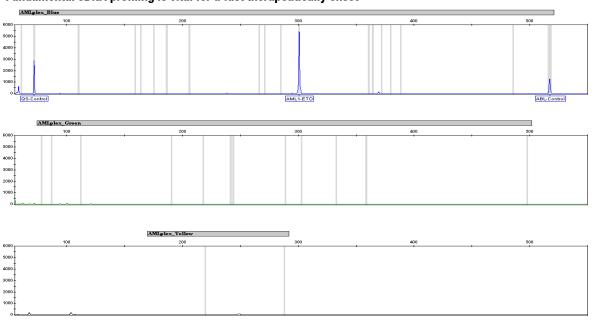
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Mentype[®] **AMLplex**^{QS} secures obtained result by two internal controls that do not require extra reagents. A Quality Sensor (QS) provides certainty that the PCR-amplification was not inhibited. The ABL-control provides information about the successfully performed RNA to cDNA reverse transcription, and, the quality of the generated cDNA template. Additionally, Mentype[®] **AMLplex**^{QS} comes with 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 cDNA profiling is vital for a fast therapeutically onset



Electropherogram of the Mentype® **AMLPlex**^{0S} control-setup using 500 ng of AML1-ETO cDNA. Analysis performed on an ABI PRISM® 3130 Genetic Analyzer with the DNA Size Standard 550 (BTO) using the GeneMapper® ID Software.

Technical specifications

Optimal amount of template cDNA per reaction: 0.2 - 1.0 μg

Volume per PCR reaction: 25 µL

Fluorescence labels: 6-FAMTM, 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
25 reactions	45-31220-0025
100 reactions	45-31220-0100
400 reactions	45-31220-0400



Diagnostic GmbH