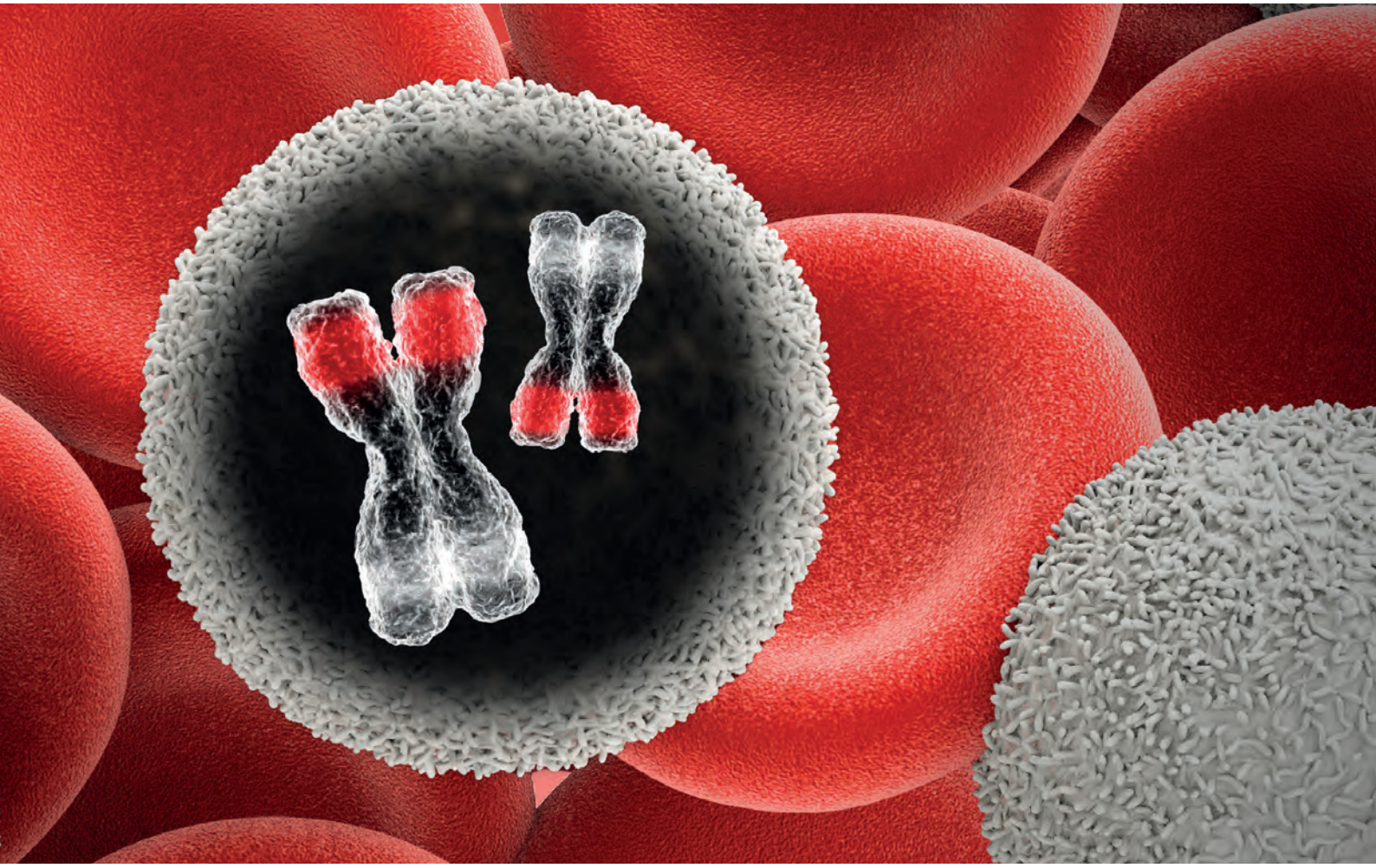
Acute Myeloid Leukemia Diagnostics

Investigate gene fusions in AML diagnostics



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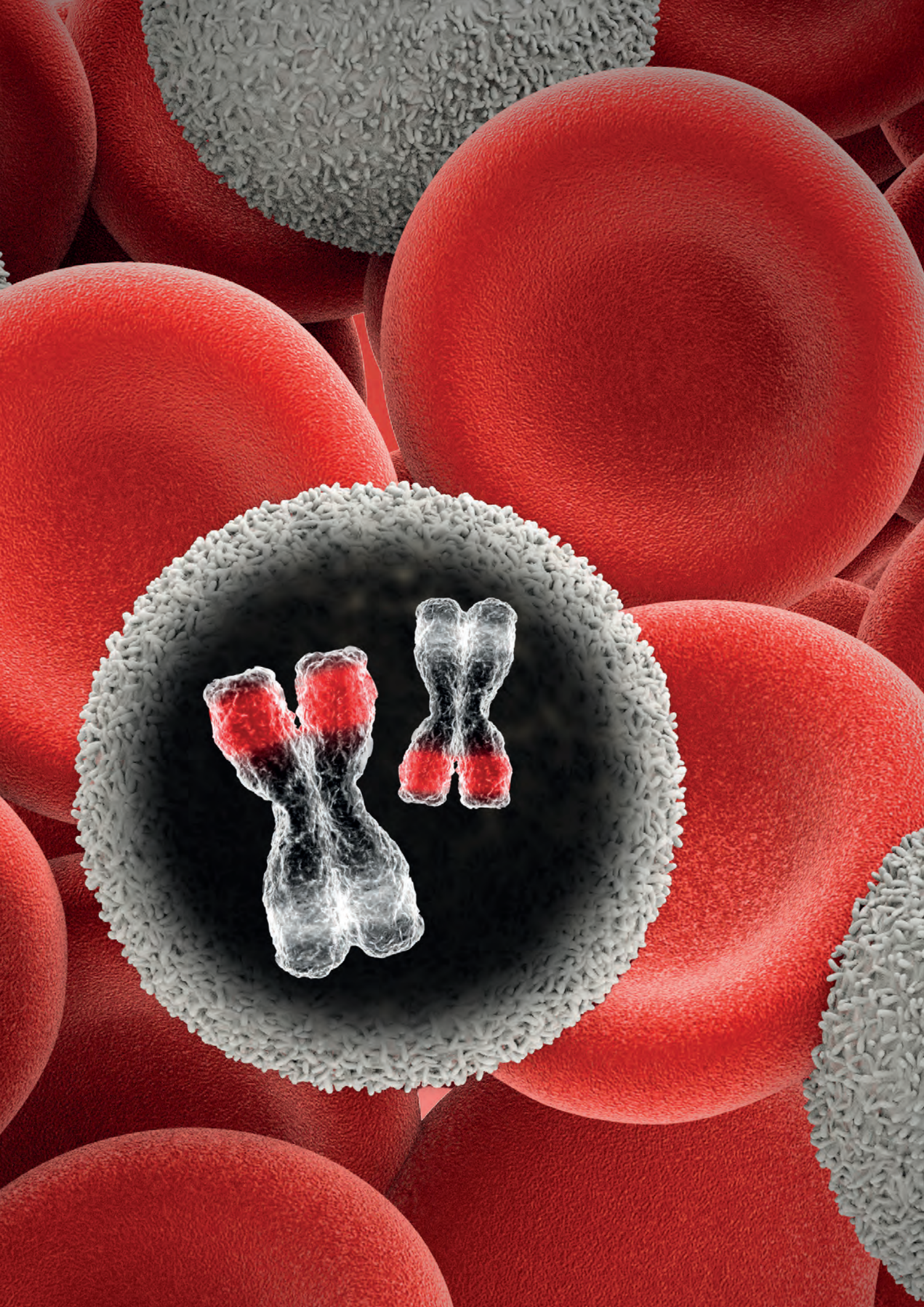


Acute Myeloid Leukemia

Molecular-based AML diagnosis, classification and prognosis

Acute Myeloid Leukemia (AML) is a biologically heterogeneous disease characterized by malignant growth within the hematopoietic system. It involves excessive proliferation of myeloid cells in the bone marrow, which leads to compromised hematopoiesis. AML incidence rises with age, the disease rapidly progresses and can become fatal within a short span, if left untreated. Therefore, a swift and accurate AML diagnosis is of utmost importance.

The evaluation of specific chromosomal aberrations has high prognostic value in nearly all types of acute leukemia. Molecular biological evidence of chromosomal aberrations (translocations) represents an important diagnostic completion. Detecting specific translocations enables the subtype classification of leukemic diseases and provides essential information for the risk-directed therapy of patients. According to the ELN Guidelines 2022[1] and WHO guidelines 2016[2] the stratification and risk categorization according to genetic abnormalities in AML is strongly recommended. Mentype® AMLplex^{QS} facilitates the detection of the most common chromosomal aberrations observed so far in AML and represents a simple-to-use, routine-fit, and reliable screening tool.

BIOTYPE AML Portfolio

- **Mentype® AMLplex^{QS} PCR Amplification Kit (IVDR)**
  Detection of 34 transcript variants of 11 gene fusions

IVD - in vitro diagnostics; IVDD – CE-IVD product in grace period, certified according to IVD Directive 98/79/EC; IVDR – CE-IVD product certified according to IVD Regulation (EU) 2017/746.

REFERENCES:

1 Döhner, H. et al. Diagnosis and management of AML in adults: 2022 recommendations from an international expert panel on behalf of the ELN. Blood 140, 1345-1377; https://doi.org/10.1182/blood.2022016867 (2022)

2 Arber, D. et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. Blood 127, 2391-2405; https://doi.org/10.1182/blood-2016-03-643544 (2016)

Acute Myeloid Leukemia 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 2022[1].

Gene Fusion	Chromosomal Aberration	Transcript Variant	Prognosis According to ELN guidelines[1]
RUNX1::RUNX1T1	t(8;21) (q22;q22)	-	Favorable[1,2]
BCR::ABL	t(9;22) (q34;q11)	e1a3 e1a2 e14a2 (b3a2) e14a3 (b3a3) e13a2 (b2a2) e13a3 (b2a3)	Adverse[1]
PICALM::MLLT10	t(10;11) (p12;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	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) (p21;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;q35)	-	
PML::RARA	t(15;17) (q24;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: 2022 recommendations from an international expert panel on behalf of the ELN.” Blood vol. 140, pp. 1345–1377, 2022.

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.

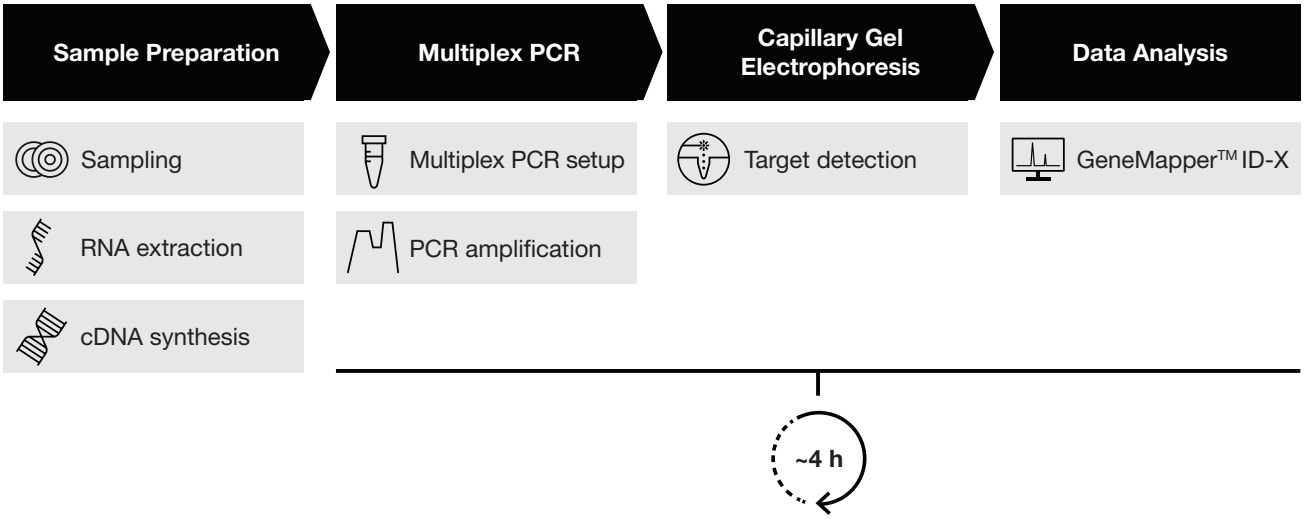
Mentype® AMLplex^{QS} PCR Amplification Kit

IVD CE 0483

EU IVDR 2017/746

Enhance laboratory efficiency with a streamlined workflow

Mentype® AMLplex^{QS} is the comprehensive multiplex approach for a fast detection of genetic aberrations associated with acute myeloid leukemia (AML). The assay helps reduce hands-on time to a minimum by detecting all 11 gene fusions within a total of 34 transcript variants in a single multiplex-PCR reaction. RNA isolated from blood or bone marrow is transcribed into cDNA and subsequently amplified using the kit's optimized components for multiplex analysis.



Mentype® AMLplex^{QS} PCR Amplification Kit workflow features

High Clinical Performance

99.5% diagnostic specificity
94.4% diagnostic sensitivity

High Throughput

Compatible with all major ABI Genetic Analyzer

Reliable Results

Secures clinical evaluation with comprehensive control concept

Fast & Simple Data Analysis

Takes minutes through intuitive evaluation of electropherograms

Mentype® AMLplex^{QS} PCR Amplification Kit

IVD CE 0483

EU IVDR 2017/746

Investigate gene fusions in AML diagnostics

Approved for in Vitro Diagnostics

Mentype® AMLplex^{QS} PCR Amplification Kit is a registered CE-IVD product according EU 2017/746 (IVDR). 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} PCR Amplification Kit, clinicians and laboratories are following those guidelines.

1 H. Döhner et al. “Diagnosis and management of AML in adults: 2022 recommendations from an international expert panel on behalf of the ELN.” Blood vol. 140, pp. 1345–1377, 2022.

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.

Simple Workflow for Fast Decision Making

The uncomplicated experimental setup allows a simple integration in the daily routine. A turn around time of ~ 4h enforces early decision making.

Comprehensive Control Concept

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

ORDER INFORMATION

Product	Size	Cat. No.	Status
Mentype® AMLplex^{QS} PCR Amplification Kit	25 reactions	45-12100-0025	IVDR
Mentype® AMLplex^{QS} PCR Amplification Kit	100 reactions	45-12100-0100	IVDR
Mentype® AMLplex^{QS} PCR Amplification Kit	400 reactions	45-12100-0400	IVDR

IVD – in vitro diagnostics; IVDD – CE-IVD product in grace period, certified according to IVD Directive 98/79/EC; IVDR – CE-IVD product certified according to IVD Regulation (EU) 2017/746.

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