Molecular Pathology

NGS – Myeloid Blood Cancer Panel

ZYTOMED® SYSTEMS

AmoyDx® Myeloid Blood Cancer Panel

Background Information

Myeloid leukemia is a malignant disease of hematopoietic stem cells. It is mainly characterized by the abnormal proliferation of primitive and juvenile myeloid cells in the bone marrow and peripheral blood.
Due to its chronic phase, chronic myeloid leukemia (CML) has a relatively slow progression. It is predominantly defined by the Philadelphia chromosome with a *BCR::ABL1* fusion. Since the approval of several tyrosine kinase inhibitors, CML is clinically well manageable [1].
Acute myeloid leukemia (AML) is a heterogeneous disease that quickly leads to death without adequate treatment. According to the World Health Organization (WHO) classification and the International Consensus Classification (ICC), the subtypes of AML are differentiated based on cytomorphological, cytogenetic and molecular genetic characteristics. The molecular genetic characteristics include gene fusions such as *CBFB::MYH11*, gene rearrangements such as of *KMT2A*, as well as gene mutations e. g. in *CEBPA*, which may also be prognostically relevant. Furthermore, mutations in e. g. *FLT3* or *IDH1/2* can predict a response to targeted therapies [2-4].

The newly available AmoyDx® Myeloid Blood Cancer Panel enables a comprehensive molecular genetic analysis of 55 genes associated with myeloid leukemia. The analysis on both DNA and RNA level permits the detection of 252 different gene fusions in addition to single nucleotide variants (SNVs), and insertions and deletions (InDels).

Information on the AmoyDx® Myeloid Blood Cancer Panel

The AmoyDx® Myeloid Blood Cancer Panel is a Next-Generation Sequencing-based assay for the qualitative detection of SNVs, InDels and fusions in 55 genes on DNA and RNA from bone marrow aspirates. The focus of this assay is on the tumor entities AML and CML, but may be further suited to characterize other hematologic malignancies. The analysis of the sequence data can be performed locally using the AmoyDx® NGS Data Analysis System (ANDAS).

This product is for research use only (RUO).

Target Genes Included in the Panel

ABL1	***ASXL1***	***BCOR***	***BRAF***	***CALR***
CBFB	***CBL***	***CEBPA***	***CREBBP***	***CSF3R***
CTCF	***DIS3***	***DNMT3A***	***ETV6***	***EZH2***
FBXW7	***FLT3***	***GATA1***	***GATA2***	***IDH1***
IDH2	***IKZF1***	***JAK2***	***JAK3***	***KIT***
KMT2A	***KRAS***	***MAX***	***MPL***	***MYC***
MYD88	***MLLT10***	***NF1***	***NPM1***	***NRAS***
NUP98	***NUP214***	***PDGFRA***	***PHF6***	***PTPN11***
RB1	***RIT1***	***RUNX1***	***RARA***	***SETBP1***
SF3B1	***SRSF2***	***STAG2***	***STIL***	***TET2***
TP53	***TCF3***	***U2AF1***	***WT1***	***ZRSR2***

SNVs & InDels (DNA-based detection)

Fusions (RNA-based detection)

SNVs, InDels & Fusions

Advantages of the AmoyDx® Myeloid Blood Cancer Panel at One Glance

Easy and Flexible
- Library preparation in only one day (1 h hands-on time)
- Several stopping possibilities
- One tube per sample (DNA & RNA)
- Only one PCR amplification and purification per reaction

Comprehensive and Targeted
- DNA and RNA input enables the analysis of SNVs and InDels as well as the detection of 252 gene fusions associated with myeloid leukemias
- Index primers are already included in the kit

Precise and Safe
- Innovative NGS technology based on "Molecular Inversion Probes"
- UID (**U**nique **ID**entifier) sequences for identifying PCR errors
- Local data analysis on the ANDAS from AmoyDx® for high data security

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Specifications of the AmoyDx® Myeloid Blood Cancer Panel

Regulatory status	RUO
Number of genes	55 genes
Genomic coverage	240 kb
Number of amplicons	1,152
Validated sequencing platforms	Illumina NextSeq® 500/550, NovaSeq® 6000, MiSeq® und MiSeq®Dx (RUO mode) *
Sample material	DNA and RNA from bone marrow aspirate specimens
Amount of DNA/RNA required per sample	DNA: ≥ 50 ng (optimal 100 ng) RNA: ≥ 200 ng (optimal 400 ng)
Variants detected	SNVs, InDels and gene fusions
Sensitivity	SNVs/InDels: 3 % allele frequency Fusions: 600 copies
Data output per sample	≥ 2.5 Gb
Working days for library preparation	1
Technology	HANDLE
Data analysis	Local workstation with the AmoyDx® analysis software (ANDAS)

*NextSeq, NovaSeq and MiSeq are registered trademarks of Illumina, Inc., 92122, San Diego, US.

Product Information

Description	Amount	Status	Order no.
AmoyDx® Myeloid Blood Cancer Panel Detection of SNVs, InDels and fusions in 55 genes on DNA and RNA from bone marrow aspirate specimens	1 Kit (24 Tests)	RUO	ADX-MBCP06-R

Local Analysis of Sequencing Data with AmoyDx® NGS Data Analysis System

Description	Status	Order no.
ANDAS (AmoyDx® NGS Data Analysis System) Packaging consisting of server (PowerEdge Server with Linux CentOS operating system) and pre-installed ANDAS analysis software	CE/IVD	ANDAS-1

Literature

[1] Hochhaus A *et al.* European LeukemiaNet 2020 recommendations for treating chronic myeloid leukemia. Leukemia. 34:966-984, 2020

[2] Arber DA *et al.* International Consensus Classification of Myeloid Neoplasms and Acute Leukemias: integrating morphologic, clinical, and genomic data. Blood 140:1200-1228, 2022

[3] Khoury JD *et al.* The 5th edition of the World Health Organization Classification of Haematolymphoid Tumours: Myeloid and Histiocytic/Dendritic Neoplasms. Leukemia 36:1703-1719, 2022

[4] 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, 2022

i In case of any questions, please contact your local sales representative or our product management team (molpath@zytomed-systems.de)

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