Molecular Pathology

NGS - Melanoma Panel

AmoyDx® HANDLE Melanoma NGS Panel

Detection of mutations in 9 melanoma key genes

The AmoyDx® HANDLE Melanoma NGS Panel is a Next-Generation Sequencing-based assay for the qualitative detection of mutations (SNVs), insertions and deletions (InDels) in nine key genes that play a decisive role in the analysis of malignant melanomas. In addition to the detection of common biomarkers such as *BRAF, NRAS, KIT, GNA11* and *GNAQ*, mutations in two critical hotspot areas of the *TERT* promoter (C228T, C250T) are also detected.

This panel enables the analysis of DNA isolated from formalin-fixed and paraffin-embedded (FFPE) tissue. As with all AmoyDx® NGS panels, the sequence data can be analyzed locally using the AmoyDx® NGS Data Analysis System (ANDAS).

Specifications of the AmoyDx® HANDLE Melanoma NGS Panel

Regulatory status	RUO
Number of genes/target regions detected	Coding regions and exon-intron junctions of 8 melanoma-relevant genes and hotspot regions in the *TERT* promoter
Genomic coverage	approx. 4.8 kb
Validated sequencing platforms	Illumina NextSeq® 500/550, MiSeq®, MiSeq®Dx (RUO mode), iSeq® 100*
Sample material	DNA from FFPE tissue
Amount of DNA required per sample	30 - 100 ng (50 ng recommended)
Parameters/variants detected	SNVs, InDels
Sensitivity	5% allele frequency
Data output per sample	25 Mb
Working days for library preparation	1
Technology	HANDLE
Data analysis	Local workstation with AmoyDx® analysis software (ANDAS)

* NextSeq®, MiSeq®, iSeq® are registered trademarks of Illumina, Inc., 92122, San Diego, US

Advantages of the AmoyDx® HANDLE Melanoma NGS Panel

- Library preparation in one working day possible
- Efficient and flexible protocol consisting of just 5 steps with multiple stopping points
- Only one PCR purification at the end of library preparation
- Use of UID (**U**nique **ID**entifier) sequences to identify PCR errors during data analysis
- Comparatively low sequencing and data storage capacity required
- High data security when analyzing on the ANDAS workstation being an independent local stand-alone system

Genes and Target Regions

Genes	*BRAF*	*CTNNB1*	*GNA11*	*GNAQ*	*HRAS*	*KIT*	*KRAS*	*NRAS*	*pTERT**
Target region	Exon 11, 15	Exon 3	Exon 4, 5	Exon 4, 5	Exon 2, 3	Exon 9, 11, 13, 17, 18	Exon 2, 3, 4	Exon 2, 3, 4	c.-124C>T(C228T), c.-146C>T(C250T)

*Two hotspot regions

This product is for research use only (RUO)

You will find our corresponding product portfolio on the back page

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HANDLE-Technology

The AmoyDx® HANDLE Melanoma NGS Panel is based on the fast HANDLE (**H**alo-Shape **AN**nealing and **D**efer- **L**igation **E**nrichment) technology. The library preparation can be done in only 5 hours (1 hour hands-on time). All reactions take place in only one tube per sample, minimizing the risk of sample mix-ups. By using UID (**U**nique **ID**entifier) sequences, PCR and sequencing artifacts can be eliminated bioinformatically in an efficient manner.

Product Information

Description	Quantity	Status	Order no.
AmoyDx® HANDLE Melanoma NGS Panel Detection of mutations (SNVs, InDels) in 9 melanoma key genes on DNA from FFPE tissue	1 Kit (24 Tests)	RUO	ADX-HCUS-01-R

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

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

Further AmoyDx® NGS-Assays Using the HANDLE-Technology

Description	Quantity	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
AmoyDx® HRD Complete Panel Detection of mutations in 20 HRR genes, including *BRCA1* and *BRCA2*, and determination of a Genomic Scar Score (GSS) to determine the HRD status of DNA from FFPE tumor tissue	1 Kit (20 Tests)	RUO	ADX-HCOM05-R
AmoyDx® HANDLE Classic NGS Panel Detection of fusions and mutations in 40 key genes in solid tumors on genomic DNA and RNA from FFPE tissue	1 Kit (24 Tests)	CE/IVD	ADX-HCNP01

If you have any questions, please contact your local sales representative or our product management team (molpath@zytomed-systems.de)

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