Molecular Pathology

HRR NGS Panel

ZYTOMED® SYSTEMS | a ZYTOMICS® company

AmoyDx® HANDLE HRR NGS Panel

Detection of mutations in 27 HRR genes

In healthy cells DNA double-strand breaks are corrected by the HRR (Homologous Recombination Repair) mechanism. If the HRR mechanism is not functional due to mutations in the HRR genes, such as *BRCA1, BRCA2* or *ATM*, loose DNA ends are joined by an alternative, non-specific repair pathway (NHEJ) instead. The result is genomic instability, that often occurs in certain tumor types, for example breast, ovarian or prostate cancer. The sequencing of HRR genes is recommended in the S3 guideline of May 2024 for advanced, hormone-refractory prostate cancer in the context of PARP inhibitor therapy. All HRR genes mentioned in the guideline are included in the AmoyDx® HANDLE HRR NGS Panel.

The CE/IVD-classified AmoyDx® HANDLE HRR NGS Panel enables the detection of mutations in 27 HRR genes as well as in hotspot regions of the *BRAF, ERBB2, KRAS, NRAS, PIK3CA* genes. The innovative HANDLE technology allows library preparation in only 5 steps within 5 hours. The NGS libraries can be sequenced on all current Illumina platforms. As with all AmoyDx® NGS assays, the sequence data is analyzed on the AmoyDx® NGS Data Analysis System (ANDAS).

▶ Target Regions of the AmoyDx® HANDLE HRR NGS Panel

AR	*HDAC2* #
*ATM** #	*HOXB13*
ATR	*KRAS*
*BARD1**	*MRE11A*
BRAF	*NBN*
*BRCA1** #	*NRAS*
*BRCA2** #	*PALB2** #
*BRIP1** #	*PIK3CA*
CDH1	*PPP2R2A**
*CDK12** #	*PTEN*
*CHEK1**	*RAD51B**
*CHEK2** #	*RAD51C**
ERBB2	*RAD51D**
ESR1	*RAD54L**
FANCA #	*STK11*
*FANCL**	*TP53*

Advantages of the AmoyDx® HANDLE HRR NGS Panels:

- CE/IVD-classified
- 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 (Unique IDentifier) sequences to identify PCR errors during data analysis
- Sequencing possible on all current Illumina platforms
- Requires a comparatively low sequencing and data storage capacity
- High data security when analyzing on the ANDAS workstation being an independent local stand-alone system

27 genes: coding regions, exon-intron transitions; *BRAF, ERBB2, KRAS, NRAS, PIK3CA:* hotspot regions

*Contains 15 genes investigated in the PROfound study for prostate cancer

Contains all genes mentioned in the S3 guideline „Prostate Cancer", Version 7.0, May 2024

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Specifications of the AmoyDx® HANDLE HRR NGS Panel

Number of covered genes/target regions	Coding regions and splicing regions of 27 HRR genes, hotspot regions of *BRAF, ERBB2, KRAS, NRAS, PIK3CA*
Genome coverage	~ 95 kb
Validated sequencing platforms	Illumina NovaSeq® 6000, NextSeq® 500, MiSeq®, MiSeq®Dx, MiniSeq®, iSeq® 100*
Sample material	DNA from FFPE tissue and blood
DNA amount per sample	30 - 100 ng for FFPE samples and 20 - 100 ng for blood samples
Detected variants	SNVs, InDels, additionally large rearrangements in *BRCA1/2* in DNA from blood
Sensitivity	5 % for somatic mutations
Data output per sample	Somatic mutations 0.7 Gb (for 5 % sensitivity) Germline mutations 0.35 Gb
Working days for library preparation	1
Technology	HANDLE
Data analysis	Local workstation with the AmoyDx® analysis software (ANDAS)

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

Product Information

Description	Amount	Status	Order no.
AmoyDx® HANDLE HRR NGS Panel Detection of mutations in 27 HRR genes, in hotspot regions of *BRAF, ERBB2, KRAS, NRAS, PIK3CA* in genomic DNA from blood and FFPE tumor tissue	1 Kit (24 Tests)	CE/IVD	ADX-HHNP02

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

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

Further AmoyDx® NGS-Assays

Description	Amount	Status	Order no.
AmoyDx® BRCA Pro Panel Detection of mutations in *BRCA1* und *BRCA2* on genomic DNA from blood and FFPE tumor tissue	1 Kit (24 Tests)	CE/IVD	ADX-NBR04
AmoyDx® HRD Focus Panel Detection of mutations in *BRCA1* und *BRCA2* and the determination of the Genomic Scar Score (GSS) to determine the HRD status on DNA from FFPE tumor tissue	1 Kit (20 Tests)	CE/IVD	ADX-HDNP03

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

Learn more: www.zytomed-systems.com

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