Molecular Pathology

NGS - HRD Complete Panel

ZYTOMED® SYSTEMS

AmoyDx® HRD Complete Panel

Detection of mutations in 20 HRR genes and determination of the HRD status

The AmoyDx® HRD Complete Panel is an advanced development of the AmoyDx® HRD Focus Panel, which is already established in many laboratories for determining homologous recombination deficiency (HRD). In both NGS assays, in addition to the *BRCA1/2* mutational status, genomic instability is determined based on 24,000 SNPs, which are evenly distributed throughout the genome. An algorithm generated by machine learning uses these SNPs to calculate a Genomic Scar Score (GSS) [1]. The GSS is already used in the AmoyDx® HRD Focus Panel and has demonstrated a high concordance with other common assays for HRD determination in independent studies and external quality assurance tests [2,3]. The AmoyDx® HRD Complete Panel can also be used to determine SNVs, InDels and homozygous deletions in 18 other genes involved in homologous recombination repair (HRR). Both assays are based on the efficient and flexible HANDLE technology of AmoyDx®. Data analysis is performed on a local workstation using the well-established AmoyDx® NGS data analysis software (ANDAS).

Specifications of the AmoyDx® HRD Complete Panel

Regulatory status	RUO
Number of genes detected/target regions	Coding regions and exon-intron boundaries of 20 HRR genes (incl. *BRCA1* and *BRCA2*) as well as 24,000 SNPs for GSS determination
Genomic coverage	approx. 1.5 Mb
Validated sequencing platforms	Illumina NextSeq® 500/550, NextSeq® 550Dx (RUO mode), NovaSeq® 6000*
Sample material	DNA from FFPE tissue
DNA amount required per sample	HRD: ≥ 50 ng HRR genes: ≥ 30 ng (100 ng for homozygote deletions)
Parameters/variants detected	HRD status, additionally SNVs, InDels and homozygote deletions in HRR genes
Sensitivity	5% allele frequency
Data output per sample	4 Gb
Working days for library preparation	1
Technology	HANDLE
Data analysis	Local workstation with the AmoyDx® analysis software (ANDAS)

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

HRR Genes Included in the Panel

*ATM**	*BARD1**	*BRCA1**	*BRCA2**	*BRIP1**	*CDH1*	*CDK12**	*CHEK1**	*CHEK2**	*FANCA*
*FANCL**	*HDAC2*	*PALB2**	*PPP2R2A**	*PTEN*	*RAD51B**	*RAD51C**	*RAD51D**	*RAD54L**	*TP53*

*Genes included in the PROfound study [4]
High risk genes for ovarian carcinoma [5]

Advantages of the AmoyDx® HRD Complete Panel

- Library preparation in only one working day possible
- Efficient and flexible protocol: only 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
- A relatively small amount of sequencing and data storage capacity required
- High data security during the analysis on the ANDAS workstation being an independent local stand-alone system

This product is for research use only (RUO).

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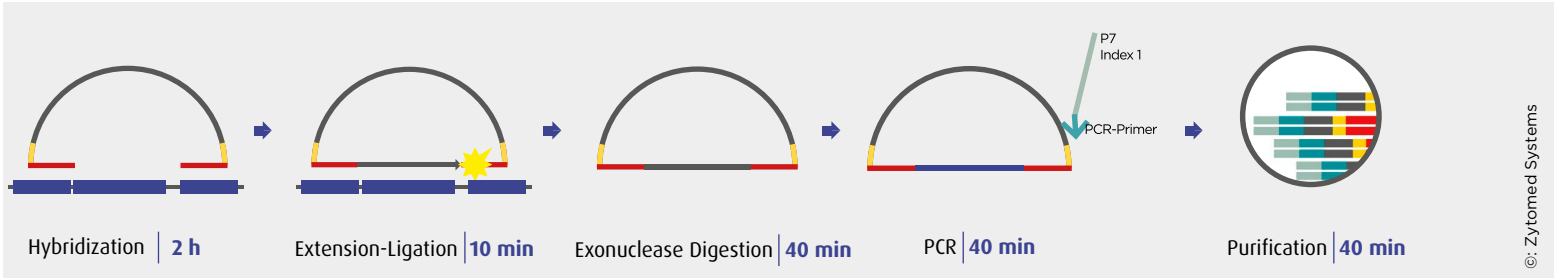
HANDLE-Technology

Similar to the AmoyDx® HRD Focus Panel, the AmoyDx® HRD Complete Panel is based on the fast HANDLE (**H**alo-Shape **AN**nealing and **D**efer-**L**igation **E**nrichment) technology. Library preparation can be completed in only 5 hours (1 hour hands-on time). All reactions take place in one reaction tube per sample, minimizing the risk of sample mix-ups. Through the use of UID (**U**nique **ID**entifier) sequences, PCR and sequencing artefacts can be eliminated bioinformatically in an efficient manner.



Product Information

Description	Amount	Status	Order no.
AmoyDx® HRD Complete Panel Detection of mutations in 20 HRR genes, incl. *BRCA1* and *BRCA2*, and determination of the Genomic Scar Score (GSS) to determine the HRD status on DNA from FFPE tumor tissue	1 Kit (20 Tests)	RUO	ADX-HCOM05-R

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® HRD Focus Panel Detection of mutations in *BRCA1* and *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
AmoyDx® BRCA Pro Panel Detection of mutations in *BRCA1* and *BRCA2* on genomic DNA from blood and FFPE tumor tissue	1 Kit (24 Tests)	CE/IVD	ADX-NBR04
AmoyDx® HANDLE HRR NGS Panel Detection of mutations in 27 HRR genes and in hotspot regions of the genes *BRAF*, *ERBB2*, *KRAS*, *NRAS* and *PIK3CA* on genomic DNA from blood and FFPE tumor tissue	1 Kit (24 Tests)	CE/IVD	ADX-HHNP02

Literature

[1] Yuan W *et al.* Genomic Scar Score: A robust model predicting homologous recombination deficiency based on genomic instability. BJOG 129(Suppl. 2):14-22, 2022

[2] Fumagalli C *et al.* In-house testing for homologous recombination repair deficiency (HRD) testing in ovarian carcinoma: a feasibility study comparing AmoyDx HRD Focus panel with Myriad myChoiceCDx assay. Pathologica 114:288-294, 2022

[3] Pfarr N *et al.* High Concordance of Different Assays in the Determination of Homologous Recombination Deficiency–Associated Genomic Instability in Ovarian Cancer. JCO Precis Oncol 8:e2300348, 2024

[4] de Bono J *et al.* Olaparib for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med 382:2091-2102, 2020

[5] S3-Leitlinie Diagnostik, Therapie und Nachsorge maligner Ovarialtumoren. Version 5.1 - Mai 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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