Molecular Pathology

HRR Liquid NGS Panel

ZYTOMED® SYSTEMS | a ZYTOMICS company

AmoyDx® HRR Liquid NGS Panel

Detection of mutations in 24 genes on cfDNA (liquid biopsy)

In healthy cells DNA double-strand breaks are repaired by the homologous recombination repair (HRR) 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, which often occurs in certain tumor types, e. g. breast, ovarian or prostate cancer. In advanced, hormone-refractory prostate cancer (mCRPC), the sequencing of HRR genes, in addition to *BRCA1* and *BRCA2*, has until now been relevant due to the approval of some PARP inhibitors by the FDA **[1,2]**. Since May 2024, sequencing of the HRR genes has also been recommended by the S3 guideline for mCRPC **[3]**.

The AmoyDx® HRR Liquid NGS Panel was specifically developed for the analysis of cfDNA from blood plasma (liquid biopsy). In this context, liquid biopsy represents a non-invasive and safe alternative to FFPE tissue. Based on the dual-directional capture technology (ddCAP, hybrid capture method), the kit comprises a two-day protocol that enables the detection of mutations in 20 HRR genes as well as *PTEN*, *AKT1, PIK3CA* and *AR*. The NGS libraries are suitable for sequencing on many Illumina platforms and can be easily combined with other NGS libraries that also contain Illumina adapters. As with all AmoyDx® NGS assays, the sequence data is analyzed on the AmoyDx® NGS Data Analysis System (ANDAS).

2025 Year of **Liquid Biopsy**

Advantages of the AmoyDx® HRR NGS Liquid Panel

- Small, cost-effective panel covering the most important HRR genes
- Flexible protocol (breaks possible at several points)
- Low sequencing costs due to comparatively low sequencing data volume
- High sensitivity (LoD up to 0.2 % mutation frequency)
- Sequencing also possible on MiniSeq® and MiSeq® (for LoD ≥ 0.5 %)
- UID (Unique IDentifier) sequences for the identification of PCR errors during data analysis
- Can be combined with other NGS libraries in one run
- High data security when analyzing on the ANDAS workstation as a local stand-alone system

Target Genes of the AmoyDx® HRR Liquid NGS Panel

AKT1	*FANCL* *
AR	*HDAC2* #
ATM * + #	*MLH1* +
ATR +	*MRE11* +
BARD1 *	*NBN* +
BRCA1 * + #	*PALB2* * + #
BRCA2 * + #	*PIK3CA*
BRIP1 * #	*PTEN*
CDK12 * + #	*RAD51B* *
CHEK1 *	*RAD51C* * +
CHEK2 * + #	*RAD51D* *
FANCA + #	*RAD54L* *

* Contains 14 of the 15 genes investigated in the PROfound study **[1]**
+ Contains all genes investigated in the Talapro-2 study **[2]**
Contains all genes mentioned in the S3 guideline „Prostate cancer“ **[3]**

This product is for research use onls (RUO).

You will find our corresponding product portfolio on the back page

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Specifications

Number of genes/ target regions detected	Coding regions and intron-exon transitions of 20 HRR genes as well as *PTEN, AKT1, PIK3CA* and *AR*
Genomic coverage	159 kb
Suitable sequencing platforms	Illumina MiniSeq®, MiSeq®, MiSeq®Dx (RUO mode), NextSeq® 500/550, NextSeq® 550Dx (RUO mode), NovaSeq® 6000*
Sample material	cfDNA from blood plasma (liquid biopsy)
Required cfDNA quantity per sample	30 ng (Minimum 5 ng)
Variants detected	SNVs, InDels
Sensitivity	With 30 ng cfDNA input: 0.2 % (High Performance) 0.5 % (Standard Performance)
Data output per sample	High Performance: 8 Gb Standard Performance: 1.5 Gb
Working days for library production	2
Technology	ddCAP
Data analysis	Local workstation with AmoyDx® analysis software (ANDAS)

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

Literature

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

[2] Agarwal N *et al.* Talazoparib plus enzalutamide in men with first-line metastatic castration-resistant prostate cancer (TALAPRO-2): a randomised, placebo-controlled, phase 3 trial. Lancet 402:291-303, 2023

[3] S3-Leitlinie Prostatakarzinom Version 7.0 – Mai 2024 AWMF-Registernummer: 043-022OL

Product Information

Description	Quantity	Technology	Status	Order no.
AmoyDx® HRR Liquid NGS Panel Detection of mutations in 24 genes on cfDNA from blood plasma (liquid biopsy)	1 Kit (24 Tests)	ddCAP	RUO	ADX-NHLP10-R

Local Analysis of Sequence 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

More AmoyDx® NGS Assays

Description	Quantity	Technology	Status	Order no.
AmoyDx® HRD Focus Panel Detection of mutations in *BRCA1* and *BRCA2* as well as determination of a Genomic Scar Score (GSS) to determine the HRD status of DNA from FFPE tumor tissue	1 Kit (20 Tests)	HANDLE	CE/IVD	ADX-HDNP03
AmoyDx® HANDLE HRR NGS Panel Detection of mutations in 27 HRR genes and in hotspot regions of the *BRAF, ERBB2, KRAS, NRAS* and *PIK3CA* genes on genomic DNA from whole blood samples and FFPE tumor tissue	1 Kit (24 Tests)	HANDLE	CE/IVD	ADX-HHNP02

If you have any questions, please contact your local sales representative or our product management team (MolPath-scientific@zytomics.com)

Find out more: www.zytomed-systems.de

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