HEVA pro CE IVD

Hereditary and somatic variants profiling in Breast and Ovary Cancer

HEVA pro

4bases HEVA pro is kit for the identification of mutations in genes related to Breast and Ovary cancer, Familial adenomatous polyposis (FAP) and hereditary nonpolyposis colorectal cancer (HNPCC) , two syndromes of colorectal cancer predisposition, inherited in an autosomal dominant fashion.

HEVA pro allows the search for variants linked to a defect in homologous recombination repair (HRD), similarly to pathogenic variants in *BRCA1 or BRCA2*. The defect in HR causes error-prone DNA repair pathways in the cell, resulting in increased genomic instability, which may be responsible for susceptibility to poly- (ADP) -ribose polymerase (PARPis) inhibitors.

HEVA pro is a kit for the analysis of 50 genes through a molecular protocol based on Next Generation Sequencing (NGS) technologies. The kit is validated for germline and somatic analysis (SNPs, indels, CNVs) of DNA extracted from blood or body tissues (fresh, frozen, FFPE, FNA) samples. HEVA pro kit contains all reagents required for the preparation of the capture of specifically designed probes and for the NGS analysis using Illumina sequencers.

TECHNOLOGY

The HEVA pro kit is part of a DNA-to-variant solution that offers streamlined content, easy-to-perform library preparation, push-button sequencing systems, and simplified data analysis.

WORKFLOW

Library preparation follows a straightforward, capture-based protocol that can be completed in as little as 36 hours, with < 3 hours hands-on time. Resulting libraries can be normalized, pooled, and then loaded on to a flow cell for sequencing. Prepared libraries are sequenced on any compatible Illumina sequencers.

Validation

To demonstrate assay capabilities, clinical samples were run in a clinical setting. DNA quality and quantity of the libraries prepared were verified using Qubit and Agilent Bioanalyzer.

Profile of the prepared libraries in Figure .

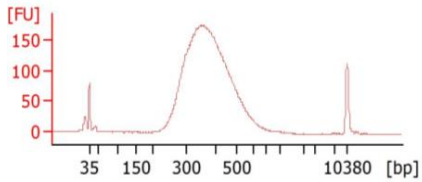

Figure 1. HEVA PRO Bioanalyzer library profile for germline samples

Table 1: List of genes in **HEVA pro**

ATM	MSH6	FAM175A	LZTR1
APC	MUTYH	MRE11	CTNNB1
BARD1	NBN	PIK3CA	KRAS
BRCA1	PALB2	PMS2CL	ERBB2
BRCA2	PMS2	XRCC2	ALK
BRIP1	PTEN	NF1	EGFR
CDH1	RAD50	SPRED1	RB1
CHEK2	RAD51C	MEN1	CDKN2A
EPCAM	RAD51D	RET	CDK4
MLH1	STK11	SMARCB1	FLCN
MSH2	TP53	NF2	RUNX1
XPC	WRN	PTCH1	CDKN1C
SMAD4	HRAS		

SAMPLE PER RUN

Instrument	Samples per run	
	Germline	Somatic
MiSeq Nano Kit v2 (300-cycles)	4	0
Nano Kit v2 (500-cycles)	4	0
Micro Kit v2 (300-cycles)	16	1
Kit v2 (300-cycles)	56	3
Kit v2 (500-cycles)	56	3
Kit v3 (600-cycles)	96	6
MiniSeq Mid Output Kit (300-cycles)	32	1
High Output Kit (300-cycles)	96	6
iSeq 100 i1 kit (300-cycles)	16	1
NextSeq 550 Mid-Output Kit	536	32
High-Output Kit	1656	96

**the estimated maximum number of samples per cartridge / chip assumes a reading depth of 300x for the germline and 5000x for the somatic. The optimal number of samples can be empirically estimated on the local setup*

Ordering Information

Product	REF
HEVA pro	C3040-16X (16 test)
HEVA pro	C3040-96X (96 test)
For Illumina instruments	
UDI Primers Set A (96 test)	7001
UDI Primers Set B (96 test)	7002
UDI Primers Set C (96 test)	7003
UDI Primers Set D (96 test)	7004
UDI Primers Set 16 (16 test)	7005