AVENIO Tumor Tissue Expanded Kit V2

Tumor Profiling: Guideline-driven and emerging biomarkers

The AVENIO Tumor Tissue Expanded Kit V2 is a next-generation sequencing (NGS) tumor profiling research assay for identifying genomic aberrations derived from solid tumors. This assay contains **77 genes,** including those currently in the U.S. National Comprehensive Cancer Network (NCCN) Guidelines.[1] This panel also contains emerging biomarkers investigated in clinical research.

Benefits

- Report all four mutation classes - SNVs, indels, fusions and CNVs from just 20 ng of amplifiable DNA.[2]
- Delivers exceptional analytical performance supported by enzymatic error suppression and molecular barcodes.[2]
- Analyze plasma containing DNA from a variety of solid tumor types using a single workflow optimized for running up to 16 samples at a time.
- Rely on a single trusted supplier for complete support of your isolations, library prep, target enrichment panels, and post-hybridization reagents.
- Receive a complete solution with the required reagents, a robust bioinformatics pipeline and software for analysis and reporting to keep your lab at the forefront of cancer research.[†]

Research focus

Lung, Colorectal, Breast, Gastric, Prostate, Glioma, Melanoma, Ovarian, Thyroid and Pancreatic

Applications

- Tumor profiling
- Detection of resistance biomarkers
- Investigation of emerging cancer biomarkers

Analytical metrics[2]

Mutation Class	SNVs		Indels		Fusions		CNVs	
Mutant Allele Frequency /Copy Number	5%		5%		5%			
Sensitivity and PPV	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV
	>99%	>99%	>99%	>99%	>99%	>99%	SD	>99%

SD: Sample dependent
Samples: FFPE tissue curls/sections, DNA input: ≥20 ng of FFPET DNA, total DNA amount for each sample determined by input QC.

Sensitivity and Positive Predictive Value (PPV) metrics based on observed product performance. Sensitivity and PPV performance reported per variant. Sensitivity was determined using commercially available reference samples containing verified mutations at the stated allele frequencies. SNV performance is panel wide. Indel, Fusion and CNV performance based on whitelist variants. AVENIO Tumor Tissue Analysis Kits V2 achieve >99.99% per base specificity across each of the panels. Stated performance requires at least 20 million reads per sample for Targeted, Expanded and Surveillance Kits V2. Sequencing performed on an Illumina® NextSeq™ 500/550/550Dx instrument.

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Specifications

Panel size	192 kb
Sample size	2x10 µm FFPET curls/sections
DNA input*	20 ng of amplifiable DNA

Reactions per kit	24
Turn-around time	5 days from extraction to results

* Total DNA amount for each sample was determined by input QC.

Assay targets

Gene	Seq Target	SNV	Indel*	Fusion**	CNV**
ABL1	Selected Regions	▪			
AKT1	Selected Regions	▪			
AKT2	Selected Regions	▪			
ALK	Selected Regions	▪	▪	▪	
APC	Selected Regions	▪	▪		
AR	All Coding Regions	▪			
ARAF	Selected Regions	▪			
BRAF	Selected Regions	▪	▪		
BRCA1	All Coding Regions	▪			
BRCA2	All Coding Regions	▪			
CCND1	All Coding Regions	▪			
CCND2	All Coding Regions	▪			
CCND3	All Coding Regions	▪			
CD274	All Coding Regions	▪			
CDK4	All Coding Regions	▪			
CDK6	Selected Regions	▪			
CDKN2A	All Coding Regions	▪			
CSF1R	Selected Regions	▪			
CTNNB1	Selected Regions	▪	▪		
DDR2	Selected Regions	▪			
DPYD	Selected Regions	▪			
EGFR	All Coding Regions	▪	▪		▪
ERBB2	All Coding Regions	▪	▪		▪
ESR1	All Coding Regions	▪			
EZH2	Selected Regions	▪			
FBXW7	All Coding Regions	▪			
FGFR1	Selected Regions	▪			
FGFR2	Selected Regions	▪		▪	
FGFR3	Selected Regions	▪		▪	
FLT1	Selected Regions	▪			
FLT3	Selected Regions	▪			
FLT4	Selected Regions	▪			
GATA3	Selected Regions	▪			
GNA11	Selected Regions	▪			
GNAQ	Selected Regions	▪			
GNAS	Selected Regions	▪			
IDH1	Selected Regions	▪			
IDH2	Selected Regions	▪			
JAK2	Selected Regions	▪			

Gene	Seq Target	SNV	Indel*	Fusion**	CNV**
JAK3	Selected Regions	▪			
KDR	Selected Regions	▪			
KEAP1	All Coding Regions	▪			
KIT	Selected Regions	▪	▪		
KRAS	All Coding Regions	▪			
MAP2K1	Selected Regions	▪			
MAP2K2	Selected Regions	▪			
MET	All Coding Regions	▪	▪		▪
MLH1	All Coding Regions	▪			
MSH2	All Coding Regions	▪			
MSH6	All Coding Regions	▪			
MTOR	Selected Regions	▪			
NF2	All Coding Regions	▪			
NFE2L2	Selected Regions	▪			
NRAS	Selected Regions	▪			
NTRK1	Selected Regions	▪		▪	
PDCD1LG2	All Coding Regions	▪			
PDGFRA	Selected Regions	▪			
PDGFRB	Selected Regions	▪			
PIK3CA	Selected Regions	▪	▪		
PIK3R1	Selected Regions	▪			
PMS2	All Coding Regions	▪			
PTCH1	Selected Regions	▪			
PTEN	All Coding Regions	▪	▪		
RAF1	Selected Regions	▪			
RB1	All Coding Regions	▪			
RET	Selected Regions	▪		▪	
RNF43	Selected Regions	▪			
ROS1	Selected Regions	▪		▪	
SMAD4	All Coding Regions	▪			
SMO	All Coding Regions	▪			
STK11	All Coding Regions	▪			
TP53	All Coding Regions	▪	▪		
TERT Promoter	Selected Regions	▪			
TSC1	Selected Regions	▪	▪		
TSC2	Selected Regions	▪			
UGT1A1***	Selected Regions	▪			
VHL	All Coding Regions	▪			

All coding regions are based on the longest transcript from Ensembl build 82.
* Indels are limited to variants in a pre-specified list of positions, referred to as "Loci of Interest", except for EGFR exon 19 long deletions, EGFR exon 20 long insertions and MET long insertions, which are not restricted to a pre-defined set of Indels.
** Detection of Fusions and CNVs are limited to variants in a pre-specified list of positions, referred to as "Loci of Interest" in the AVENIO analysis software.
*** UGT1A1*28 allele sequenced but not currently called by the AVENIO analysis software.

AVENIO family of NGS Oncology Assays

AVENIO Tumor Tissue Expanded Kit V2 is a part of the AVENIO family of NGS oncology research assays that include three tumor tissue and three corresponding ctDNA assays. By using the wider family of AVENIO assays, labs can obtain detailed molecular findings across all four mutation classes from tissue or plasma samples.

1. National Comprehensive Cancer Network. http://www.nccn.org. August 2, 2023.
2. Data on file with Roche.

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†Required hardware: Illumina® NextSeq™ 500/550/550Dx and Roche Oncology Analysis Server. NextSeq™ 500/550/550Dx instruments and associated sequencing reagents are manufactured and sold by Illumina and are not supplied by Roche.

For more information about the AVENIO Tumor Tissue Analysis Kits, please contact your local Roche Sequencing representative.

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