AVENIO ctDNA Targeted Kit V2

Tumor Profiling: Guideline-driven biomarkers

The AVENIO ctDNA Targeted Kit V2 is a next-generation sequencing (NGS) liquid biopsy tumor profiling research assay for identifying genomic aberrations in solid tumors. This assay contains **17 genes,** including those in the U.S. National Comprehensive Cancer Network (NCCN) Guidelines.[1]

Benefits

- Report all four mutation classes - SNVs, indels, fusions and CNVs from just 10-50 ng of cfDNA.[2]
- Delivers exceptional analytical performance supported by integrated digital error suppression (iDES) strategies, combining molecular barcodes with in silico error suppression techniques.[2,3]
- 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.
- Reduce operational complexity by obtaining reagents for cfDNA isolation from plasma, library prep and target enrichment from a single trusted vendor.
- 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, Glioma, Melanoma, Ovarian, Thyroid and Pancreatic

Applications

- Non-invasive tumor profiling
- Non-invasive detection of resistance biomarkers

Analytical metrics[2]

Mutation Class	SNVs		Indels		Fusions		CNVs**	
Mutant Allele Frequency /Copy Number	0.5%*		1.0%*		1.0%			
Sensitivity and PPV	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV
	>99%	>99%	>99%	>99%	>99%	>99%	SD	>99%

SD: Sample dependent
* Detects variants down to 0.1%
**Can detect ERBB2, EGFR and MET CNVs. Performance dependent on input sample type and input concentration (10 ng - 50 ng per reaction).

Performance samples: Seraseq ctDNA Complete Mutation Mixes (SeraCare), healthy donor cfDNA.

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 data based on hotspot calls. The AVENIO ctDNA Analysis Kit V2 can achieve >99.99% per base specificity across each of the panels. Stated performance requires at least 40 million reads per sample for all AVENIO ctDNA Panels V2. Sequencing performed on an Illumina® NextSeq™ 500/550/550Dx instrument.

For Research Use Only. Not for use in diagnostic procedures.

Specifications

Panel size	81 kb
Sample size	4 ml of plasma
cfDNA input	10-50 ng

Reactions per kit	16
Turn-around time	5 days from extraction to results

Assay targets

Gene	Seq Target	SNV	Indel*	Fusion**	CNV**
ALK	Selected Regions	▪	▪	▪	
APC	Selected Regions	▪	▪		
BRAF	Selected Regions	▪	▪		
BRCA1	All Coding Regions	▪			
BRCA2	All Coding Regions	▪			
DPYD	Selected Regions	▪			
EGFR	All Coding Regions	▪	▪		▪
ERBB2	All Coding Regions	▪	▪		▪
KIT	Selected Regions	▪	▪		

Gene	Seq Target	SNV	Indel*	Fusion**	CNV**
KRAS	All Coding Regions	▪			
MET	All Coding Regions	▪	▪		▪
NRAS	Selected Regions	▪			
PDGFRA	Selected Regions	▪			
RET	Selected Regions	▪		▪	
ROS1	Selected Regions	▪		▪	
TP53	All Coding Regions	▪			
UGT1A1***	Selected 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 ctDNA Targeted Kit V2 is a part of the AVENIO family of NGS oncology research assays that include three ctDNA and three corresponding tumor tissue assays. By using the wider family of AVENIO assays, labs can obtain detailed molecular findings across all four mutation classes from plasma or tissue samples.

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For more information about the AVENIO ctDNA Analysis Kits, please visit our website or contact your local Roche Sequencing representative.

†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.

1. National Comprehensive Cancer Network. http://www.nccn.org. August 2, 2023.
2. Data on file with Roche.
3. Newman AM, Lovejoy AF, Klass DM, et al. Integrated digital error suppression for improved detection of circulating tumor DNA. Nature Biotechnology. 2016;34(5):547–555. doi:10.1038/nbt.3520.

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