AVENIO ctDNA Expanded Kit V2

Tumor profiling: Guideline-driven and emerging biomarkers

The AVENIO ctDNA Expanded Kit V2 is a next-generation sequencing (NGS) liquid biopsy tumor profiling research assay for identifying genomic aberrations derived from solid tumors. This panel 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 trials.

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 a variety of solid tumor indications for research using a single optimized DNA workflow for 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.
- 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 indications

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

Applications

- Non-invasive tumor profiling
- Non-invasive detection of resistance biomarkers
- Investigation of emerging cancer 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	
	>99%	>99%	>99%	>99%	>99%	>99%	

*The reported sensitivity and PPV is for 50 ng DNA input at the stated AF%. The kit has the ability to report variants down to 0.1% AF (with lower sensitivity), and can make libraries with as low as 10 ng.
**The kit reports ERBB2, EGFR, and MET CNVs. Performance is dependent on various factors, including sample type, input DNA amount, percent tumor content, and the individual tumor's genomic copy number. Our technical study detected CNVs at dPCR-verified copy numbers, using a commercially available reference sample (50 ng). CNV specificity was high (PPV >99%). ERBB2 detected at 4.5 copies, MET detected at 4.5 copies.

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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 (Research Use Only mode) instrument.

Specifications

Panel size	192 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
Product/Material Number	09733779001

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 ctDNA Expanded 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.

1. National Comprehensive Cancer Network. http://www.nccn.org. October 1, 2025.
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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Published by:

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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 ctDNA Analysis Kits, please contact your local Roche representative.

MC--10894 10/2025