AVENIO ctDNA Surveillance Kit V2

Tumor burden monitoring and MRD detection

The AVENIO ctDNA Surveillance Kit V2 is an NGS liquid biopsy research assay that is specially designed to enable researchers to monitor tumor burden in lung and colorectal cancer over time, as well as to assess for minimal residual disease (MRD). This assay contains **471 frequently mutated regions** associated with the presence of disease across **197 genes**, including those in the U.S. National Comprehensive Cancer Network (NCCN) Guidelines.[1]

Benefits

- Provides variant information for four mutation classes: SNVs, indels, fusions, and CNVs.
- Delivers exceptional analytical performance supported by integrated digital error suppression (iDES) strategies, combining molecular barcodes with *in silico* error suppression techniques.[2,3]
- Uses an intelligent algorithm that applies population-scale data from multiple cancer databases to design a panel with broad patient coverage.[3]
- Enables researchers to detect mutations derived from a variety of solid tumor indications using a single, streamlined workflow.†
- Maximizes the number of mutations detected per tumor while minimizing the panel size, enabling researchers to use the combined power of multiple mutations to increase the detection of ctDNA several fold while minimizing sequencing costs.

Research indications

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

Applications

- Non-invasive tumor profiling
- Non-invasive detection of resistance biomarkers
- Non-invasive serial tumor burden monitoring
- Non-invasive detection of minimal residual disease

Analytical metrics[4]

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.

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

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	198 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	09733817001

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.

Frequently mutated select regions of these genes included to monitor tumor burden (n=180)												
ABCC5	C6orf118	CSMD1	DOCK3	FCRL5	GSX1	ITGA10	LRFN5	NEUROD4	PCDH15	RNASE3	ST6GALNAC3	USH2A
ABCG2	CA10	CSMD3	DSC3	FOXG1	HACD1	ITSN1	LRP1B	NFE2L2	PDYN	ROBO2	STK11	USP29
ACTN2	CACNA1E	CTNNB1	DSCAM	FRYL	HCN1	KCNA5	LRRC7	NLGN4X	PDZRN3	SEMA5B	SV2A	VPS13B
ADAMTS12	CDH12	CTNND2	EGFLAM	GBA3	HCRTR2	KCNB2	LRRTM1	NLRP3	PGK2	SLC18A3	T	WBSCR17
ADAMTS16	CDH18	CYBB	EPHA5	GBP7	HEBP1	KCNC2	LRRTM4	NMUR1	PHACTR1	SLC39A12	THSD7A	WIPF1
ARFGEF1	CDH8	DCAF12L1	EPHA6	GJA8	HECW1	KCNJ3	LTBP4	NOL4	PIK3CA	SLC6A5	TIAM1	WSCD2
ASTN1	CDH9	DCAF12L2	EYS	GPR139	HS3ST4	KCTD8	MAP2	NPAP1	PIK3CG	SLC8A1	TMEM200A	ZC3H12A
ASTN2	CDKN2A	DCAF4L2	FAM135B	GRIA2	HS3ST5	KEAP1	MAP7D3	NR0B1	PKHD1L1	SLITRK1	TNFRSF21	ZFPM2
AVPR1A	CHRM2	DCLK1	FAM151A	GRIK3	HTR1A	KIAA1211	MKRN3	NRXN1	POLE	SLITRK4	TNN	ZIC1
BCHE	CNTN5	DCSTAMP	FAM71B	GRIN2B	HTR1E	KIF17	MMP16	NXPH4	POM121L12	SLITRK5	TNR	ZIC4
BPIFB4	CNTNAP2	DDI1	FAT1	GRIN3B	HTR2C	KIF19	MTX1	NYAP2	PREX1	SLPI	TRHDE	ZNF521
BRINP2	CPXCR1	DLGAP2	FBN2	GRM1	IFI16	KLHL31	MYH7	OPRD1	RALYL	SMAD4	TRIM58	ZSCAN1
BRINP3	CPZ	DMD	FBXL7	GRM5	IL7R	KPRP	MYT1L	P2RY10	RFX5	SOX9	TRPS1	
C6	CRMP1	DNTTIP1	FBXW7	GRM8	INSL3	LPPR4	NAV3	PAX6	RIN3	SPTA1	UGT3A2	

AVENIO family of NGS Oncology Assays

AVENIO ctDNA Surveillance 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. 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.
3. Newman AM, Bratman SV, To J, et al. An ultrasensitive method for quantitating circulating tumor DNA with broad patient coverage. Nature Medicine. 2014;20(5):548–554. doi:10.1038/nm.3519.
4. Data on file with Roche.

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

Published by:

Roche Sequencing Solutions, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

sequencing.roche.com/avenio

†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 visit our website or contact your local Roche representative.

MC--10895 10/2025