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 research kit 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 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.[2,3]

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

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.

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

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