

AVENIO Tumor Tissue Surveillance Kit V2

Longitudinal Tumor Burden Monitoring and MRD Detection



The AVENIO Tumor Tissue Surveillance Kit V2 is an NGS research assay that is designed to enable researchers to establish a baseline for tumor burden monitoring in lung and colorectal cancer, 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.²
- Delivers exceptional analytical performance supported by enzymatic error suppression and molecular barcodes.²
- Uses an intelligent algorithm that applies population-scale data from multiple cancer databases to design a panel with broad coverage.²
- Enables researchers to detect aberrations derived from a variety of solid tumor indications using a single, streamlined workflow.[†]
- Establishes baseline tumor profiles to enhance subsequent tumor burden monitoring using ctDNA.

Research focus

Primary: Lung, Colorectal

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

Applications

- Tumor profiling
- Detection of resistance biomarkers
- Establishment of a baseline for tumor burden monitoring
- Detection of minimal residual disease (MRD)

Analytical metrics²

| 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 FFPE 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.

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

Specifications

| | | | |
|-------------|-----------------------------|-------------------|-----------------------------------|
| Panel size | 198 kb | Reactions per kit | 24 |
| Sample size | 2x10 µm FFPE sections/curls | Turn-around time | 5 days from extraction to results |
| DNA input* | 20 ng of amplifiable DNA | | |

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

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 Tumor Tissue Surveillance 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.

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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.

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