AVENIO NGS Oncology Assays

Comprehensive genomic profiling (CGP), targeted profiling, and surveillance & monitoring of solid tumors for clinical research.

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

FOUNDATION MEDICINE®

Roche

A versatile solution to meet your research needs

AVENIO NGS Oncology Assay kits provide researchers a versatile solution for tumor tissue and ctDNA analysis with an integrated end-to-end workflow. With accurate and reliable analysis of ultra low ctDNA detection as well as formalin-fixed paraffin-embedded (FFPE) tissue samples, AVENIO NGS Oncology Assays offer laboratories in-house tumor profiling, comprehensive genomic profiling (CGP), and surveillance & monitoring. Each kit includes reagents for DNA extraction, sample input QC (for tissue), library preparation, target enrichment, robust bioinformatics, secondary analysis and reporting (variant calls).

Select the assay that best meets your research needs

A portfolio of high-performance kit-based assays for in-house tumor profiling, comprehensive genomic profiling (CGP), and surveillance & monitoring for clinical research.

Tumor Profiling | **Surveillance & Monitoring**

Targeted Profiling

Tissue **AVENIO Tumor Tissue Targeted Kit V2**

Plasma **AVENIO ctDNA Targeted Kit V2**

- 17 genes (81 kb)
- Contains genes in NCCN Guidelines[1]
- Detects all four mutation classes: SNVs, InDels, fusions and CNVs
- Matched tissue and liquid biopsy (ctDNA) panels

Expanded Targeted Profiling

Tissue **AVENIO Tumor Tissue Expanded Kit V2**

Plasma **AVENIO ctDNA Expanded Kit V2**

- 77 genes (192 kb)
- Includes 17 guideline-driven biomarkers[1] and 60 emerging biomarkers investigated in clinical trials
- Detects all four mutation classes: SNVs, InDels, fusions and CNVs
- Matched tissue and liquid biopsy (ctDNA) panels

Comprehensive Genomic Profiling (CGP)

Tissue **AVENIO Tumor Tissue CGP Kit**
Powered by FOUNDATIONONE®

For tissue samples only

- 324 genes (1.8 Mb)
- Designed to match the content of the 324 gene FoundationOne® CDx panel
- Detects all four mutation classes: SNVs, InDels, rearrangements and CNAs
- Detects genomic signatures: TMB, MSI and LOH

Tumor Burden Monitoring and MRD Detection

Tissue **AVENIO Tumor Tissue Surveillance Kit V2**

Plasma **AVENIO ctDNA Surveillance Kit V2**

- 197 genes (198 kb)
- Smart panel design: contains 180 algorithmically-defined biomarkers for longitudinal monitoring of tumor burden and MRD assessment
- Also contains 17 genes in NCCN Guidelines[1]
- Detects all four mutation classes: SNVs, InDels, fusions and CNVs
- Matched tissue and liquid biopsy (ctDNA) panels

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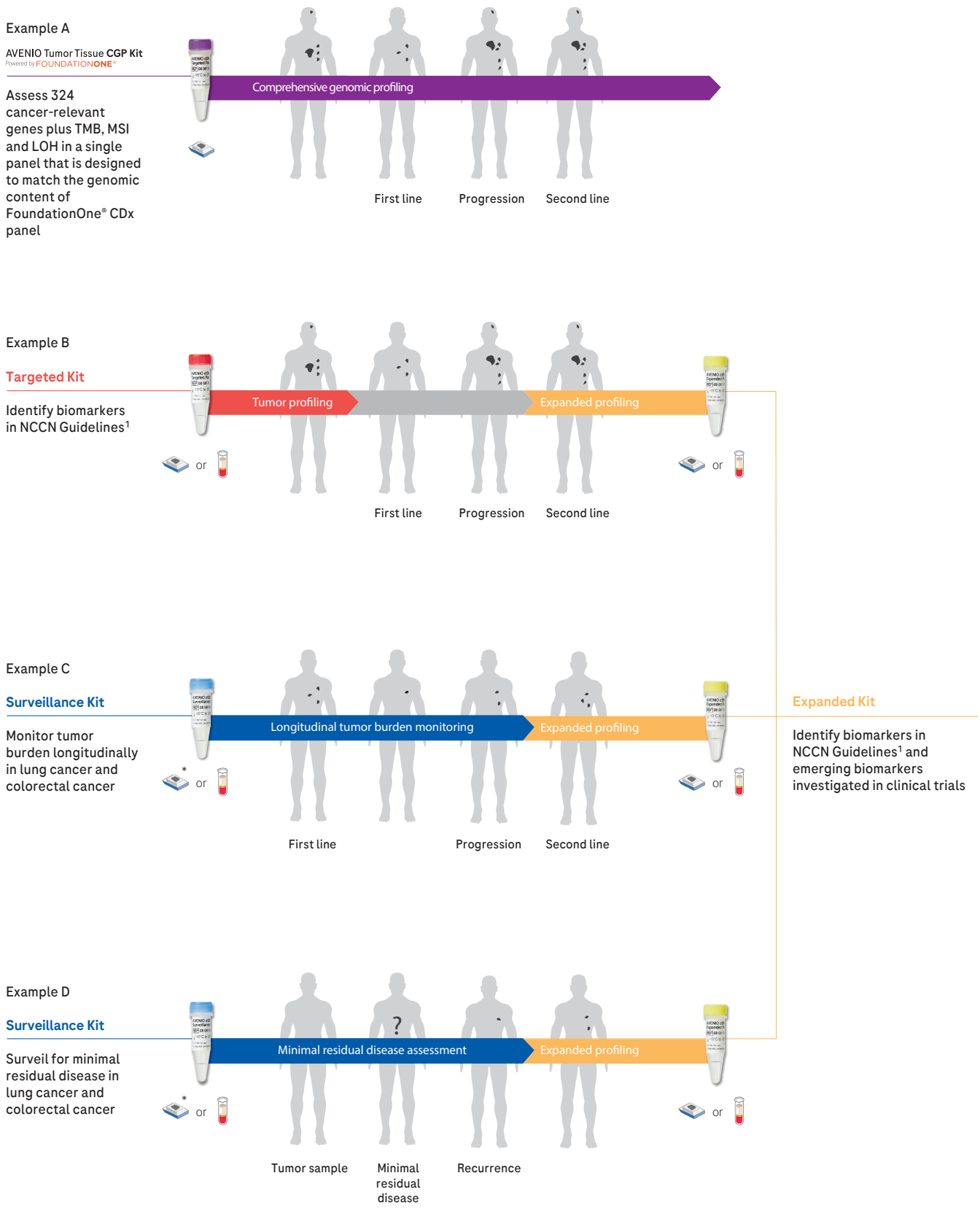
[1] National Comprehensive Cancer Network. http://www.nccn.org. Accessed Aug 29, 2023.

Example research use cases



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* The ctDNA Surveillance Kit V2 may also be used if a tumor tissue sample is available.

[1] National Comprehensive Cancer Network. http://www.nccn.org. Accessed 29 August, 2023.

Performance you expect from Roche and Foundation Medicine

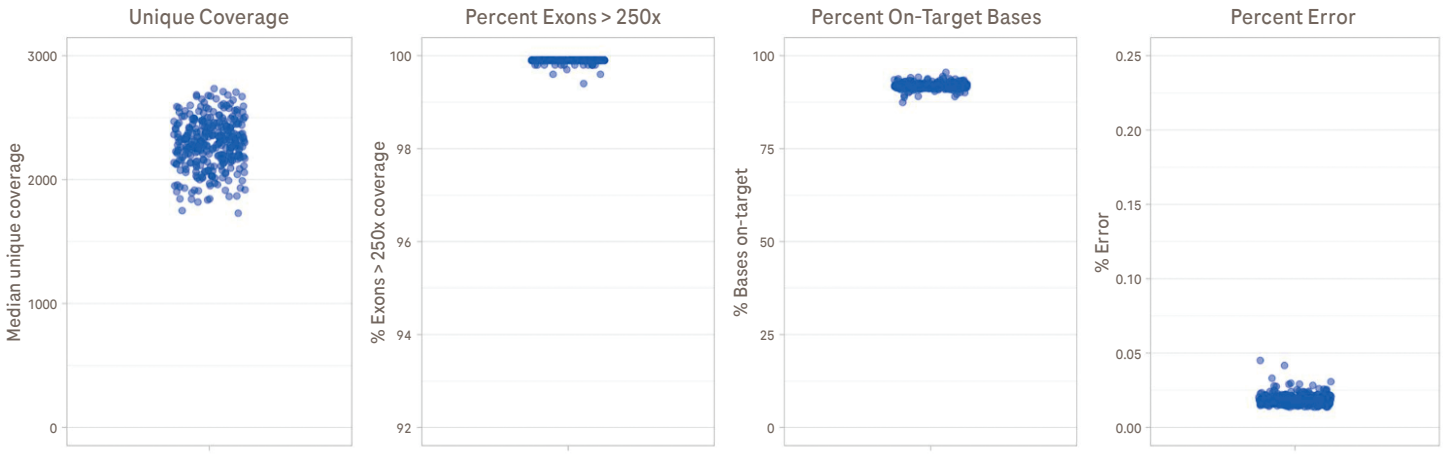
AVENIO Tumor Tissue CGP Kit: Analytical variant detection performance across genomic alterations and signatures

Libraries were prepared from 314 FFPE-derived DNA samples by the AVENIO Tumor Tissue CGP kit. For each alteration classification, the percentage of expected variants that were detected by the AVENIO Tumor Tissue CGP kit are shown. For genetic signatures, the percentage of expected samples detected as MSI, TMB, and LOH high assessment are shown.

Classification	Detected Variants/Signatures
Short Variants	98.2%
Rearrangements	90.5%
CNA	94.8%
MSI high	100%
TMB high	100%
LOH high	96.8%

Exceptional Performance as demonstrated by Key Sequencing Metrics

Libraries were prepared from 314 FFPE-derived DNA samples by the AVENIO Tumor Tissue CGP kit. Eight samples were sequenced per NextSeq 500 High-output flowcell. The graphs show sequencing QC metrics from the FoundationOne® Analysis Platform.



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Data on file with Roche.

FFPE, Formalin-fixed paraffin-emb dded. QC, Quality control. CNA, copy number alterations. MSI, Microsatellite instability. TMB, Tumor mutational burden. LOH, Loss of heterozygosity.

An integrated solution for an end-to-end hybrid-capture workflow

The efficient, high-quality AVENIO workflow includes all sample prep reagents, input QC (tissue only), robust bioinformatics and secondary analysis all from single trusted source. It has been optimized to minimize hands on time, and deliver high-quality results in just 5 days, making it easy for you to obtain reliable genomic insights about solid tumors in your lab.

5 day workflow from DNA isolation to data analysis

Day 1	Day 2	Day 3	Day 4	Day 5
DNA Isolation	Library Generation	Target Enrichment	Sequencing	Analysis & Report

AVENIO Tumor Tissue Analysis Kits V2

AVENIO Tumor DNA Isolation and QC Kit

AVENIO Tumor Library Prep Kit V2

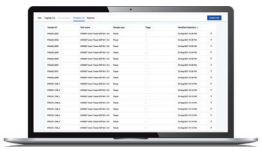
AVENIO Tumor Target Enrichment Kit V2
and
AVENIO Tumor Sample Primers (Plate A or B)

AVENIO Tumor Tissue Targeted, Expanded, and Surveillance Panel V2
and
AVENIO Tumor Post-Hybridization Kit V2

AVENIO Tumor Cleanup and Capture Beads V2

GATCTAGATTC
GGTCCAGATTC
GATCCAGCTTC
CATCCAGATTC
GATACAGATTC
GATCCAGATGC

Illumina NextSeq 500/550/550Dx and MiSeq System



With Tumor Tissue Targeted, Expanded, or Surveillance Panels: AVENIO Oncology Analysis Software Requires Oncology Analysis Server

AVENIO Tumor Tissue CGP Kit

AVENIO Tumor DNA Isolation and QC Kit

AVENIO Tumor Library Prep Kit

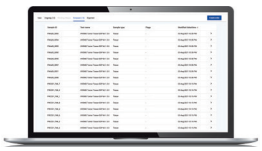
AVENIO Tumor Target Enrichment Kit
and
AVENIO Tumor Sample Primers (Plate A or B)

AVENIO Tumor Tissue Targeted, CGP Panel
and
AVENIO Tumor Post-Hybridization Kit

AVENIO Tumor Cleanup and Capture Beads

GATCTAGATTC
GGTCCAGATTC
GATCCAGCTTC
CATCCAGATTC
GATACAGATTC
GATCCAGATGC

Illumina NextSeq 500/550/550Dx System



With CGP Panel, cloud-based FoundationOne Analysis Platform

AVENIO ctDNA Analysis Kits V2

AVENIO cfDNA Isolation Kit V2

AVENIO ctDNA Library Prep Kit V2

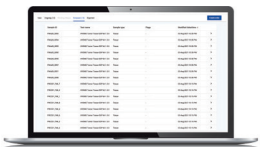
AVENIO ctDNA Enrichment Kit V2

AVENIO ctDNA Targeted, Expanded, and Surveillance Panels V2

AVENIO ctDNA Post-Hybridization Kit V2

GATCTAGATTC
GGTCCAGATTC
GATCCAGCTTC
CATCCAGATTC
GATACAGATTC
GATCCAGATGC

Illumina NextSeq 500/550/550Dx and MiSeq System



With ctDNA Targeted, Expanded, or Surveillance Panels: AVENIO Oncology Analysis Software Requires Oncology Analysis Server

Exceptional performance[1]

Rigorously optimized using thousands of samples, AVENIO assays deliver the level of performance you expect from Roche, a world leader and trusted partner in oncology.

AVENIO Tumor Tissue Analysis Kits V2

Mutant Allele Frequency/ Copy Number	SNVs		Indels		Fusions		CNVs	
	5%		5%		5%			
AVENIO Tumor Tissue Kit V2	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV
Targeted	> 99%	> 99%	> 99%	> 99%	> 99%	> 99%	Sample dependent	> 99%
Expanded	> 99%	> 99%	> 99%	> 99%	> 99%	> 99%	Sample dependent	> 99%
Surveillance	> 99%	> 99%	> 99%	> 99%	> 99%	> 99%	Sample dependent	> 99%

Samples: FFPE tissue curls/sections, DNA input: ≥20 ng of FFPET DNA, total DNA amount for each sample determined by input QC.

Sensitivity and Positive Predictive Value (PPVmetrics 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.

AVENIO ctDNA Analysis Kits V2

Mutant Allele Frequency/ Copy Number	SNVs		Indels		Fusions		CNVs**	
	0.5%*		1.0%*		1.0%			
AVENIO Tumor Tissue Kit V2	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV
Targeted	> 99%	> 99%	> 99%	> 99%	> 99%	> 99%	Sample dependent	> 99%
Expanded	> 99%	> 95%	> 99%	> 99%	> 99%	> 99%	Sample dependent	> 99%
Surveillance	> 99%	> 99%	> 99%	> 99%	> 99%	> 99%	Sample dependent	> 99%

* 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.

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[1] Data on file with Roche.

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Bring the power of Roche and Foundation Medicine* into your lab

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Proven Technology

Comprehensive Portfolio

Trusted Expertise

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*for the AVENIO Tumor Tissue CGP Kit only.

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Bring our expertise in-house at **sequencing.roche.com/aveniocgpkit** or contact your local Roche representative for more information.

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