



## AVENIO Tumor Tissue CGP Kit

Powered by **FOUNDATIONONE**®

# Bring the Power of Foundation Medicine® and Roche into Your Lab.

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**FOUNDATION  
MEDICINE**®



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# Our AVENIO Tumor Tissue CGP Kit

Leveraging the FoundationOne® comprehensive genomic profiling (CGP) secondary analysis platform and the AVENIO workflow, our kit is part of Roche's broad portfolio that offers flexible solutions to meet your research needs so you can get deeper genomic insights about solid tumors right in your lab – and advance discovery.



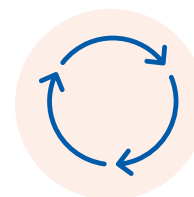
## Meaningful Genomic Insights for In-House Research

Analyzes 324 relevant genes, 4 classes of genomic alterations, and genomic signatures including TMB, MSI, and LOH.



## Proven Expertise of Roche + Foundation Medicine®

Expertise in personalized medicine and comprehensive genomic profiling: 500+ peer-reviewed publications, and 500,000 clinical samples profiled in 100+ cancer types.<sup>17</sup>



## Integrated End-to-End Workflow Solution

One workflow from DNA isolation to secondary analysis that covers all 4 classes of genomic alterations including DNA-based rearrangement detection—no separate workflow required.

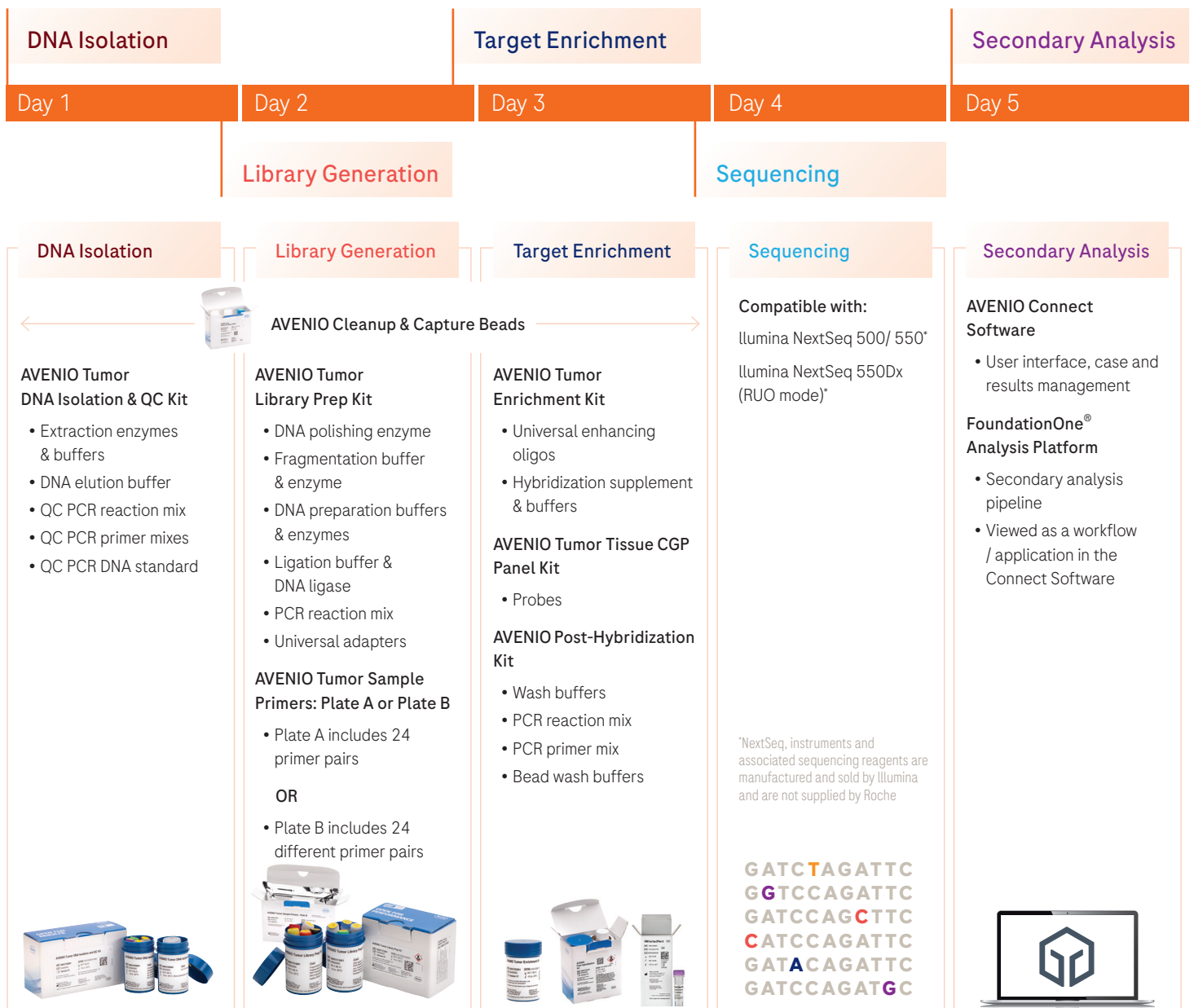
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TMB tumor mutational burden; MSI, microsatellite instability; LOH, loss of heterozygosity.

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

The efficient, high quality AVENIO workflow includes the reagents for nucleic acid extraction, input QC, library preparation, and target enrichment, and includes robust bioinformatics and secondary analysis all from one trusted source. It has been optimized to minimize hands-on time, and delivers 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



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Data on file  
 QC, Quality control.



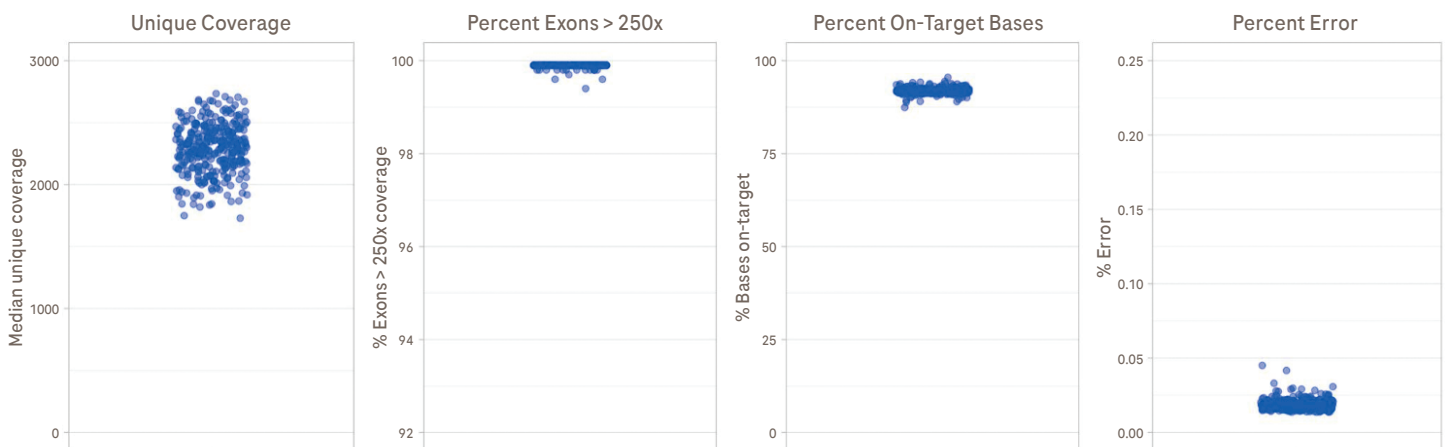
# Analytical variant detection performance across genomic alterations and signatures

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 is shown. For genetic signatures, the percentage of expected samples detected as MSI, TMB, and LOH high assessment is 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<sup>®</sup> Analysis Platform.



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Data on file

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

# Overall Kit performance across disease ontologies for all 4 mutation classes

Libraries were prepared from 314 FFPE-derived DNA samples by the AVENIO Tumor Tissue CGP kit. The expected and observed number of samples from a subset of key disease ontologies and gene mutations are shown. The range of the allele fraction, copy number, or breakpoint reads of those samples, as measured by the AVENIO Tumor Tissue CGP Analysis, are shown.

Disease Ontology	Genes	Mutations	No. Samples expected	No. Samples observed	Measured Allele Fraction, Copy Number or Breakpoint Reads
non-small cell lung carcinoma	EGFR	T790M	6	6	9.3% - 51.3%
non-small cell lung carcinoma	EGFR	L858R	11	11	9.6% - 33.9%
non-small cell lung carcinoma	EGFR	Exon 19 deletion	9	9	17.2% - 69.4%
non-small cell lung carcinoma	EGFR	G719A	1	1	28.5%
non-small cell lung carcinoma	MET	Exon 14 splice mutation	2	2	22.6% - 89.4%
non-small cell lung carcinoma	BRAF	V600E	7	7	7.0% - 17.4%
colon adenocarcinoma	BRAF	V600E	7	7	8.3% - 30.6%
melanoma	BRAF	V600E/V600K	11	11	8.5% - 65.0%
colon adenocarcinoma	KRAS	Codon 12 mutation	10	10	12.7% - 43.0%
colon adenocarcinoma	KRAS	Codon 13 mutation	5	5	19.0% - 62.3%
colon adenocarcinoma	KRAS	Codon 61 mutation	3	3	30.3% - 33.7%
colon adenocarcinoma	NRAS	Codon 13 mutation	4	4	10.6% - 45.3%
colon adenocarcinoma	NRAS	Codon 61 mutation	2	2	17.4% - 46.7%
breast cancer	PIK3CA	C420R/E542K/E545D/Q546K/H1047R/H1047L	14	14	1.0% - 62.2%
breast cancer	ERBB2	ERBB2 amplification	8	8	5 - 133 copies
non-small cell lung carcinoma	ALK-EML4	ALK-EML4 fusion	4	4	3.4% - 7.4% / 26 - 85 reads

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Data on file

FFPE, Formalin-fixed paraffin-embedded.



# Leveraging proven technology: a powerful combination

For laboratories that perform research on solid tumors.

## AVENIO workflow

A versatile, integrated end-to-end NGS workflow solution with exceptional performance\* for in-house research.

### Platform / Technology

Illumina NextSeq 500/550 instrument  
Illumina NextSeq 550 DX (RUO mode)

### Sample Type

- FFPE tissue curls or slides
- Extracted FFPET DNA

## AVENIO Tumor Tissue CGP Panel

Designed to match the content of the 324-gene FoundationOne® CDx panel:

- Detects 4 classes of genomic alterations: SNVs, InDels, rearrangements, and CNAs
- Detects genomic signatures TMB, MSI, LOH

## FoundationONE® Analysis Platform

Post-sequencing secondary analysis software makes it easy for customers to analyze samples to identify variants across various solid tumor types.

Evidence-driven variant calling knowledge base for secondary analysis, leveraging insights from over 500,000+ clinical samples.

- Broad genomic coverage
- Confidence in high-quality results
- Filtered variant calls and QC metrics
- Cloud-based computing for efficient analysis

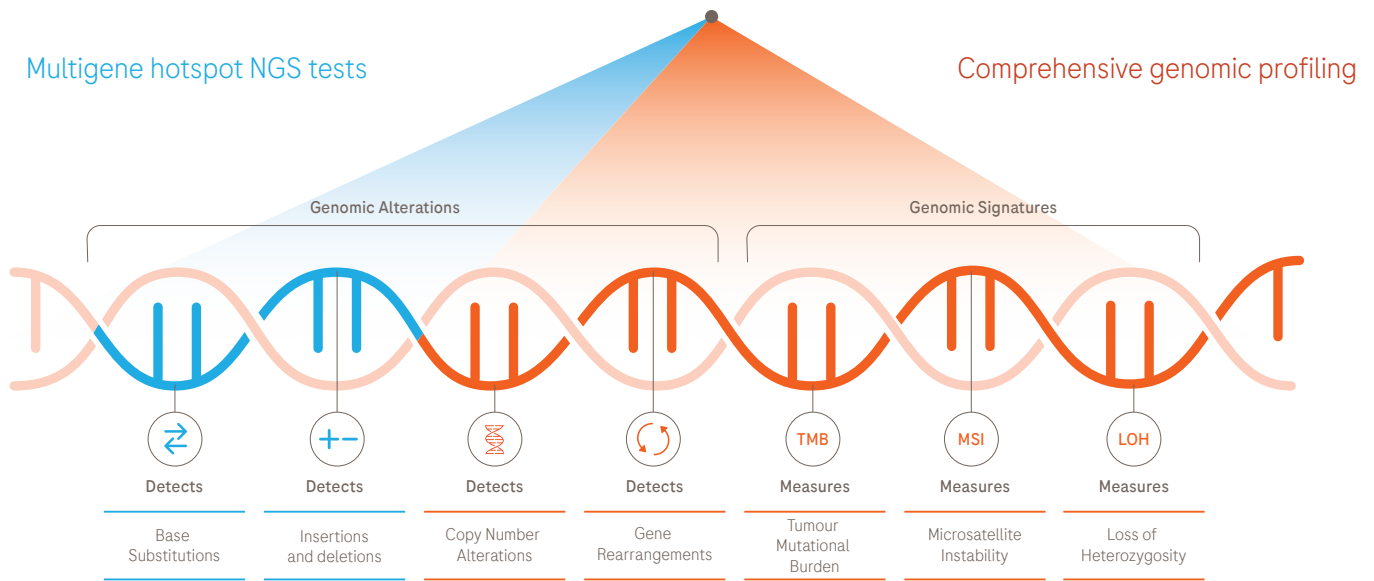
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\*Data on file

FFPET, Formalin-Fixed Paraffin-Embedded Tissue; SNV, single-nucleotide variants; InDel, insertions and deletions; CNA, copy number alterations; TMB tumor mutational burden; MSI, microsatellite instability; LOH, loss of heterozygosity

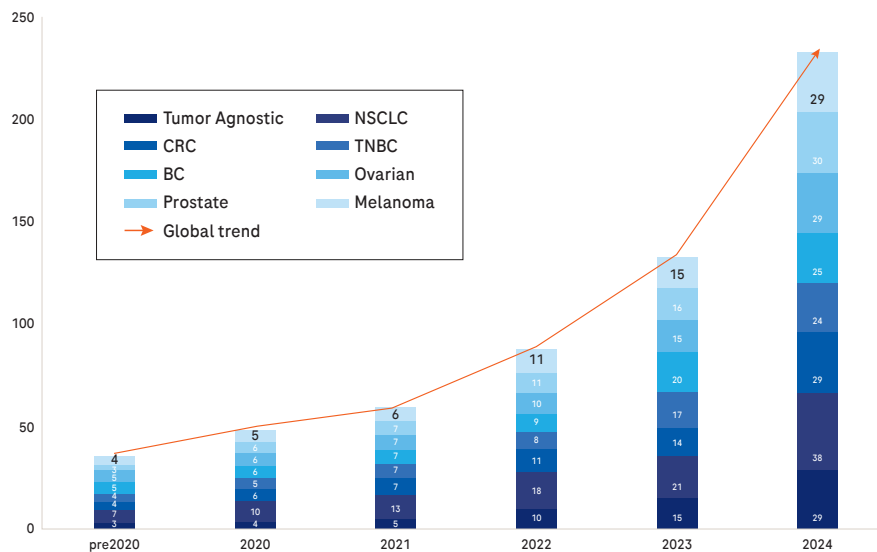
# The power of precision medicine

CGP offers the greatest insights from a single assay leveraging NGS to broadly analyze regions of the tumor genome that other tests miss.<sup>1-11</sup>



The majority of cancer research is now focused on targeted therapies, and, as a result, CGP is becoming the tool of choice.<sup>12</sup>

Potential approvals of cancer treatments targeting actionable genomic drivers from ongoing clinical trial programmes



Based on phase II and III clinical trials initiated prior to 1 February 2020 and information available as of 1 June 2020. Projection assumes that all ongoing trials lead to approvals. Multiple secondary sources used to cross-validate information, including Trialstrove, Clinicaltrials.gov, European Union Drug Regulating Authorities Clinical Trials Database, and Chinese Clinical Trial Registry; FDA approval timeline estimated as 8 months after phase III primary completion date. CGP, comprehensive genomic profiling; FDA, US Food and Drug Administration.

NCCN recommends NGS testing for a wide range of cancer types.<sup>13-15</sup> ESMO Precision Medicine Working Group recommends that clinical research centers perform multigene sequencing in the context of molecular screening programs to increase access to innovative drugs and speed up clinical research.<sup>16</sup>

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CGP, comprehensive genomic profiling. NGS, Next generation sequencing. NCCN, National comprehensive cancer network. ESMO, European society for medical oncology.

# Backed by the trusted expertise and proven technology of Roche and Foundation Medicine®

The AVENIO Tumor Tissue CGP Kit is part of Roche's extensive CGP portfolio that offers flexible solutions to meet your research needs.



Proven  
Technology



Comprehensive  
Portfolio



Trusted  
Expertise

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  17. Foundation Medicine® About us: <https://www.foundationmedicine.com/info/detail/our-story>
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Bring our expertise in-house at [go.roche.com/aveniocgpkkit](https://go.roche.com/aveniocgpkkit)  
or contact your local Roche Sequencing representative for more information.