AVENIO Tumor Tissue CGP Kit
Powered by FOUNDATIONONE®

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

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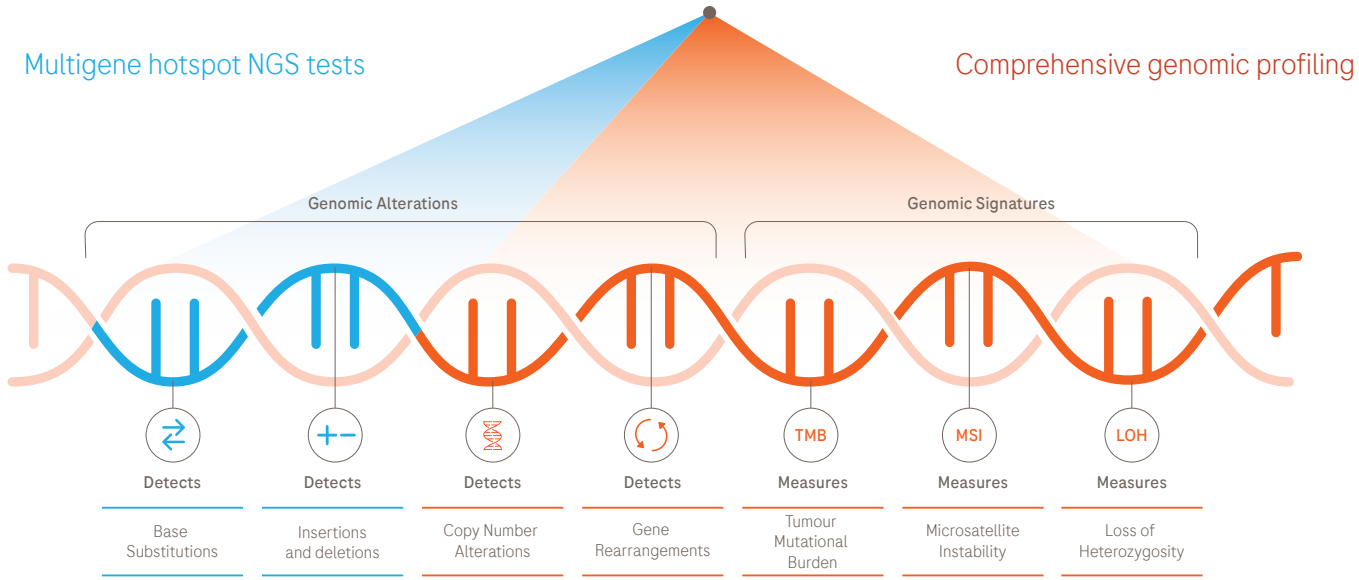
FOUNDATION MEDICINE®

Roche

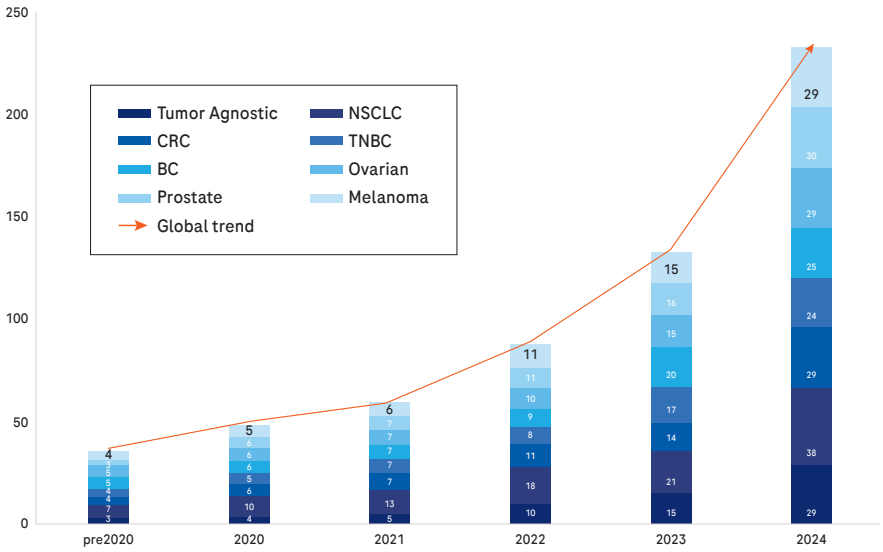
The power of precision medicine

CGP offers insights from a single assay leveraging NGS to broadly analyze regions of the tumor genome that other tests miss.[1-11]



The majority of cancer research is now focused on targeted therapies, and, as a result, CGP is becoming the tool of choice.[12]

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 Trialtrove, 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.[13-15] 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.[16]

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

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 and support services 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 relevent genes, 4 classes of genomic alterations, and genomic signatures including TMB, MSI, and LOH.

Proven Expertise of Roche + Foundation Medicine®

Experts in personalized medicine and comprehensive genomic profiling: 500+ peer reviewed publications, 500,000 clinical samples profiled in 100+ cancer types.[17]

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.

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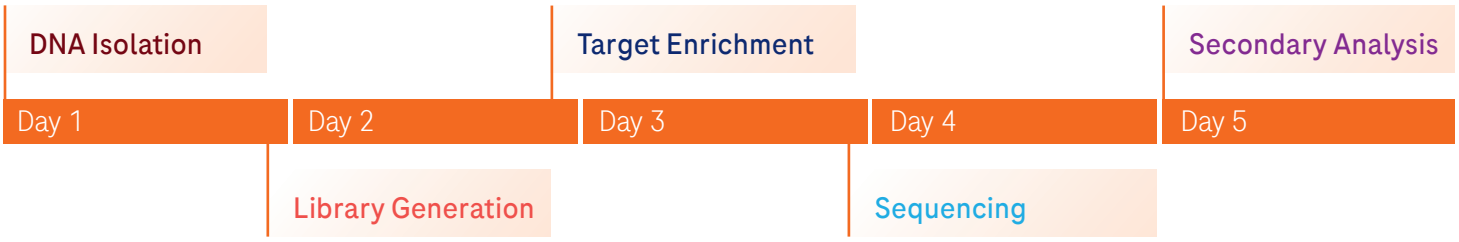
Data on file
FFPET, Formalin-Fixed Paraffin-Embedded Tissue; SNV, single-nucleotide variants; Indel, insertions and deletions; CNA, copy number alterations; TMB tumor mutational burden; MSI, microsatellite instability; LOH, loss of heterozygosity

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

The efficient, high quality AVENIO workflow includes all sample prep reagents, input QC, robust bioinformatics and secondary analysis all from one 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



DNA Isolation

AVENIO Tumor DNA Isolation & QC Kit

- Extraction enzymes & buffers
- DNA elution buffer
- QC PCR reaction mix
- QC PCR primer mixes
- QC PCR DNA standard

Library Generation

AVENIO Cleanup & Capture Beads

AVENIO Tumor Library Prep Kit

- DNA polishing enzyme
- Fragmentation buffer & enzyme
- DNA preparation buffers & enzymes
- Ligation buffer & DNA ligase
- PCR reaction Mix
- Universal adapters

AVENIO Tumor Sample Primers: Plate A or Plate B

- Plate A includes 24 primer pairs

OR

- Plate B includes 24 different primer pairs

Target Enrichment

AVENIO Tumor Enrichment Kit

- Universal enhancing oligos
- Hybridization supplement & buffers

AVENIO Tumor Tissue CGP Panel Kit

- Probes

AVENIO Post-Hybridization Kit

- Wash buffers
- PCR reaction mix
- PCR primer mix
- Bead wash buffers

Sequencing

Compatible with:

Illumina NextSeq 500/ 550*

Illumina NextSeq 550Dx (RUO mode)*

*NextSeq, instruments and associated sequencing reagents are manufactured and sold by Illumina and are not supplied by Roche

GATCTAGATTC
GGTCCAGATTC
GATCCAGCTTC
CATCCAGATTC
GATACAGATTC
GATCCAGATGC

Secondary Analysis

AVENIO Connect Software

- Connect SW v1.0 orderable by customer
- User interface, case and results management

FoundationOne Analysis Platform

- Secondary analysis pipeline
- Viewed as a workflow / application in the Connect Software

Firewall - Required

- Fortigate 50e

Gateway - Required

- Facilitate cloud / lab connection

Cobas Link 2 - Recommended

- Remote service

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Data on file
QC, Quality control.

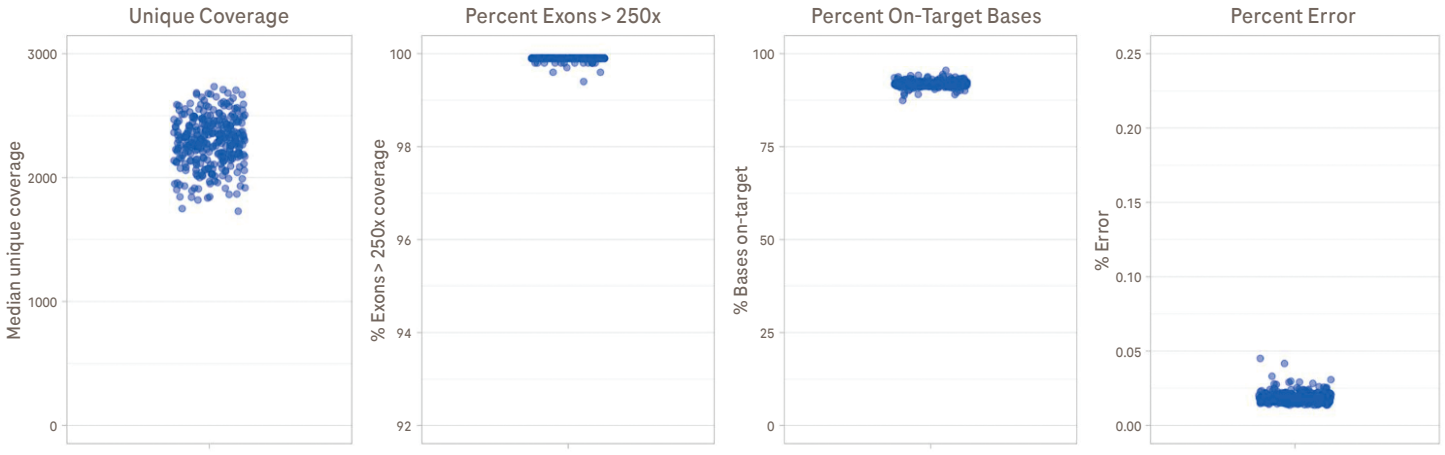
Analytical variant detection performance across genomic alterations and signatures

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 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

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-ELM4	ALK-ELM4 fusion	4	4	3.4% - 7.4% / 26 - 85 reads

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Data on file

FFPE, Formalin-fixed paraffin-embedded.

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 and comprehensive support services 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 **sequencing.roche.com/aveniocgpkit**
or contact your local Roche representative for more information.