FOUNDATION MEDICINE | Roche

LET US TAKE
**THE NIGHT SHIFT**

# The AVENIO Tumor Tissue CGP Automated Kit

Bring comprehensive genomic profiling into your lab and experience up to 24 hours of uninterrupted walkaway time with automation.

**AVENIO** Tumor Tissue CGP Automated Kit
Powered by **FOUNDATION MEDICINE**

The AVENIO Tumor Tissue CGP Kit portfolio is for Research Use Only. Not for use in diagnostic procedures.

# Crucial genomic insights hold the key to cancer research. But the process of uncovering them can be challenging.

Cancer is a disease of the genome[1], which is why comprehensive genomic profiling (CGP), a next generation sequencing (NGS) approach, has become a test of choice in cancer research.[2] However, the process of performing CGP can be complex, potentially obscuring the path to these crucial insights.

## Practical challenges of CGP can hinder the path to discovery

Error-prone manual processes.[3]

Complexities around both diverse samples of varying quality, quantity and data analysis.[3]

Bioinformatics expertise required to filter and analyze vast amounts of genomic data.[3]

Staff shortages and steep learning curve for skills related to CGP.

## As your partners, Roche and Foundation Medicine understand that time-consuming and cumbersome CGP workflows can hinder breakthroughs.

* Multiple secondary sources used to cross validate information, including Trialtrove, clinicaltrials.gov, EudraCT, ChiCTR; FDA approval timeline estimation based on Ph3 PCD + 8 months review; analysis based on current Phase ½, Phase 2 and Phase 3 trials with inclusion criteria requiring patient selection based on alterations to specific biomarkers; assumption made that all ongoing trials will lead to approval.

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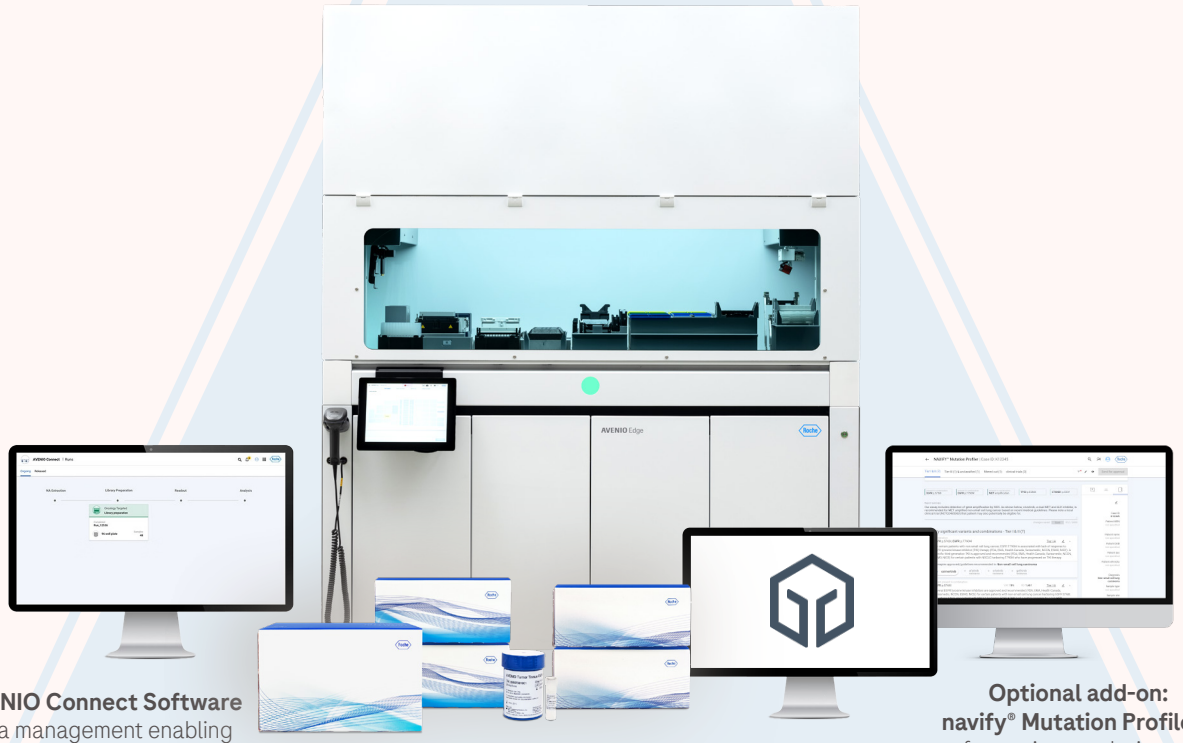
# The AVENIO Tumor Tissue CGP Automated Kit: Focus on the breakthroughs, not the process.

The AVENIO Tumor Tissue CGP Automated Kit workflow includes:

**True Walkaway Automation**

**AVENIO Edge Liquid Handler**



**AVENIO Connect Software** data management enabling secondary analysis.

**Optimized reagents** for DNA extraction and pre-filled, barcoded reagent cartridges for library preparation, target enrichment, and pooling.

**FoundationOne® Analysis Platform** for secondary analysis.

**Optional add-on: navify® Mutation Profiler***, for tertiary analysis and report generation.

**Robust Performance**

**Insight Excellence**

**Leverage a comprehensive solution that enables a simplified and efficient end-to-end CGP workflow.[4]**

*Tertiary analysis with navify® Mutation Profiler is not part of the AVENIO Tumor Tissue CGP Automated Kit and may be purchased as an add-on.
AVENIO Tumor Tissue CGP Automated Kit, AVENIO Connect Software, AVENIO Edge reagents and workflows, and navify® Mutation Profiler are for Research Use Only, Not for use in diagnostic procedures.

# Experience **true walkaway automation** and regain time for higher-value tasks.

**The AVENIO Edge Liquid Handler** is a fully automated system for NGS library preparation, target enrichment, on-deck quantification, normalization, and pooling.[4]

## Set up your AVENIO Edge Liquid Handling System run before your shift ends

**1**

Create an AVENIO Edge System work order file that includes detailed sample information

**2**

Load the instrument with barcoded samples, reagents and consumables

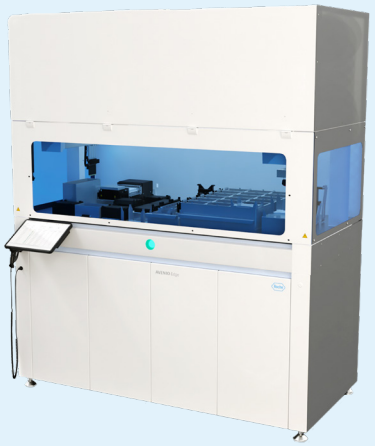
**3**

Walk away and return to collect normalized, pooled, sequencing-ready libraries

## And leave the system to do the rest

## AVENIO Edge Liquid Handling System enables:

- **Automation-Ready Reagent Cartridges**[7]
  Pre-filled, barcoded reagent cartridges provide efficiency while also minimizing the risk of error associated with manual pipetting.
- **True Walkaway Automation**[4]
  Streamlined, walk-away automation of library preparation, target enrichment, on-deck normalization and pooling.
- **Pre-Programmed AVENIO CGP Automated Workflow**[4]
  We handle the programming for the AVENIO Tumor Tissue CGP workflow and other KAPA workflows, so you don't have to.
- **Data Integrity**
  21 CFR Part 11 compliant; logs and stores user permissions, reagent details, start and stop times, and more in PDF format for traceability.



The AVENIO Tumor Tissue CGP Kit portfolio and AVENIO Edge reagents and workflows are for Research Use Only. Not for use in diagnostic procedures.

# Make your mark in advancing cancer research with **fewer manual touchpoints.***

An end-to-end CGP workflow – from DNA extraction to result generation – with only 3.5 hours of hands-on time.[5]

| | | Hands-on time | On instrument time |
|---|---|---|---|
| Day 1 | Tissue Digestion & Sample Input Plate Preparation | 60 minutes | 8 hours (overnight) |
| Day 2 | Automated Library Preparation & Enrichment | 60 minutes | 24 hours (overnight) |
| Day 3 | Sample Library QC | 15 minutes | 30 minutes |
| | Automated Library Pooling | 15 minutes | 20 minutes |
| Day 4 | Sequencing Preparation & Sequencing | 50 minutes | 25 hours |
| Day 5 | Analysis Submission & Data Retrieval via AVENIO Connect | 10 minutes | 12 hours |
| **Total hands-on time** | **Only 3.5 hours of total hands on time (HOT) within a 4.5-day workflow.[5]** | | |

QC - Quality Check

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* When compared to AVENIO Tumor TIssue CGP Kit V2.

# Achieve **robust performance** – even with challenging samples.[6]

Have confidence in every run with a CGP assay that is extensively analytically validated across **>5000 FFPE tumor samples.**[6]

**Initial Attempt Pass Rate 93.8%**[4]

**Overall sample pass rate 99.3%**[4]

Increase efficiency and potentially reduce the need for retesting so you can save time and resources without compromising the quality of your results.

**DNA extraction from FFPE tissue, delivering high quality DNA and yields.**[6]

Perform comprehensive genomic analysis that potentially expands the range of samples suitable for analysis and improves overall performance.

**High sequencing performance metrics with an average median coverage of 2,000x**[6]

Enhance data accuracy and reliability, and drive confident results with high sequencing metrics.

**High analytical sensitivity**[6]

**MAF* LoD** of 1.0-3.1% for key short variants**[4]

**High analytical specificity**[6]

**>99.99% for genomic alterations and signatures**[4]

Achieve reliable results with robust sensitivity and specificity that reduces the likelihood of false negatives.

**Consistent precision with proven lot-to-lot reproducibility**[6]

Reduce variability and increase confidence in your data across multiple experiments.

*MAF - Mutant allele frequency. **LoD - Limit of Detection.

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# Deliver **insight excellence** and generate clear, meaningful genomic insights with ease.

Bring the power of two leaders in oncology, Roche and Foundation Medicine, into your lab.[7,8]

ATCGGCA
TTTGGCC
CGCATCG
GACTACG

## Designed to be comprehensive

- Provides genomic information such as Single Nucleotide Variants **(SNVs),** Insertions and Deletions **(InDels),** Copy Number Alterations **(CNAs)** and **DNA-based gene fusions** along with genomic signatures such as Tumor Mutational Burden **(TMB)**, Microsatellite Instability **(MSI)**, genomic Loss of Heterozygosity **(gLOH)**, in addition to Homologous Recombination Deficiency Signature **(HRDsig)**.[7]
- Uses a 335-gene panel that is **aligned with the FoundationOne® CDx panel design**.[4]
- Enable DNA-based rearrangement/fusion detection with Foundation Medicine's **baitset design**.[4,9]

## Designed to elevate the value of your data

- Uncover new insights with a **pan-cancer HRD signature** that is aligned with the HRD biomarker, developed and analytically validated in the **FoundationOne®** CDx assay using real-world data and machine learning from Foundation Medicine's knowledgebase.[4]
- Access to the most critical, up-to-date, evidence-based information with **navify® Mutation Profiler*** as an add-on.[10]

## Designed to keep you future-ready

- Harness the power of **FoundationOne® Analysis Platform**, a secondary analysis platform with continuously expanding insights, consistent accuracy, and efficient cloud-based computing.[4]
- **AVENIO Connect Software**, a cloud-based solution, providing a streamlined interface to the secondary analysis software ensuring seamless data management.[11]

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# The AVENIO Tumor Tissue CGP Automated Kit: Powerful, precise, and proven with >5000 samples[6]

AVENIO Tumor Tissue CGP Automated Kit enables your lab to adopt CGP and overcome important hurdles that could hinder discoveries. With the expertise and proven technology of Roche and Foundation Medicine, you can perform CGP with efficiency and renewed confidence.

### True Walkaway Automation

Experience up to 24 hours of uninterrupted walkaway time and dedicate more attention to higher value tasks.[4]

Only 3.5 hrs of hands-on time for the end-to-end workflow[4,5]

### Robust Performance

Overcome sample complexity and have confidence in the quality of your results.[4]

Overall sample pass rate of 99.3%[4]

### Insight Excellence

Access insights and translate your data into actionable information of research value.[5,7]

Growing knowledge and technology of Roche and Foundation Medicine, two leaders in oncology[7,8]

**Cancer is a complex disease. Keep the path to discovery simple with the AVENIO Tumor Tissue CGP Automated Kit.**


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