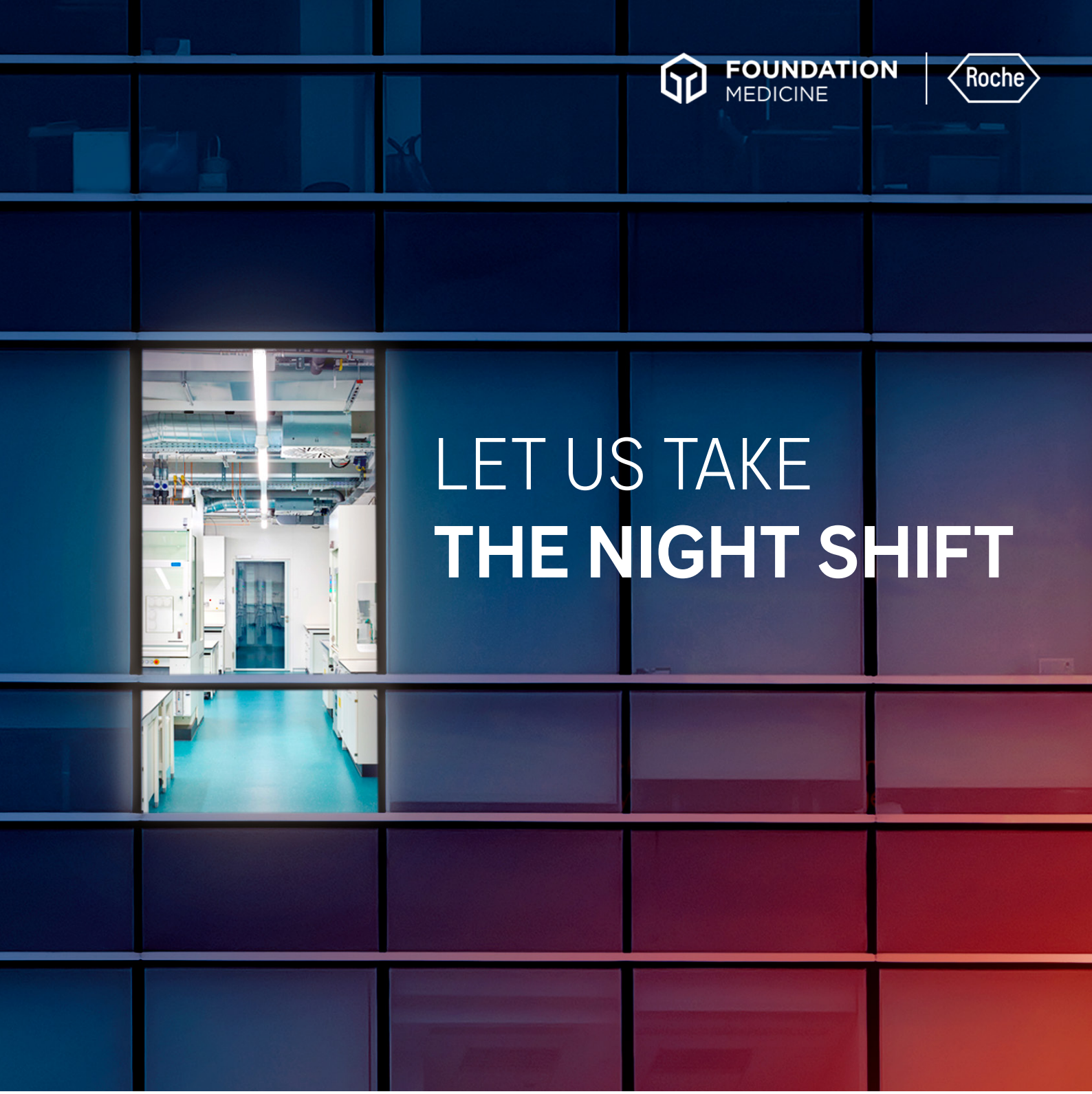
FOUNDATION MEDICINE | Roche



LET US TAKE **THE NIGHT SHIFT**

The AVENIO Tumor Tissue CGP Automated Kit

Bring comprehensive genomic profiling into your lab and experience >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 clinical cancer research.[2] ESMO guidelines recommend NGS for obtaining crucial cancer insights.[3,4] However, the process of performing CGP can be complex, potentially obscuring the path to these crucial insights.

Potential of CGP

Detects **pathogenic known variants of the four main classes** of genomic alterations and genomic signatures.

Delivers insights that inform research or treatment decisions across all cancer types. **Up to 93 unique CGP relevant biomarkers across all solid tumors by 2028.***

Increasingly favorable coverage and reimbursement pathways. **Of 78 countries, 45 have some form of NGS reimbursement.[6]**

CGP adoption barriers

Error-prone and time consuming manual processes.[5]

Complexities around diverse samples of varying quality, quantity and data analysis.[5]

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 get in the way of breakthroughs.

ESMO, European Society for Medical Oncology.
* 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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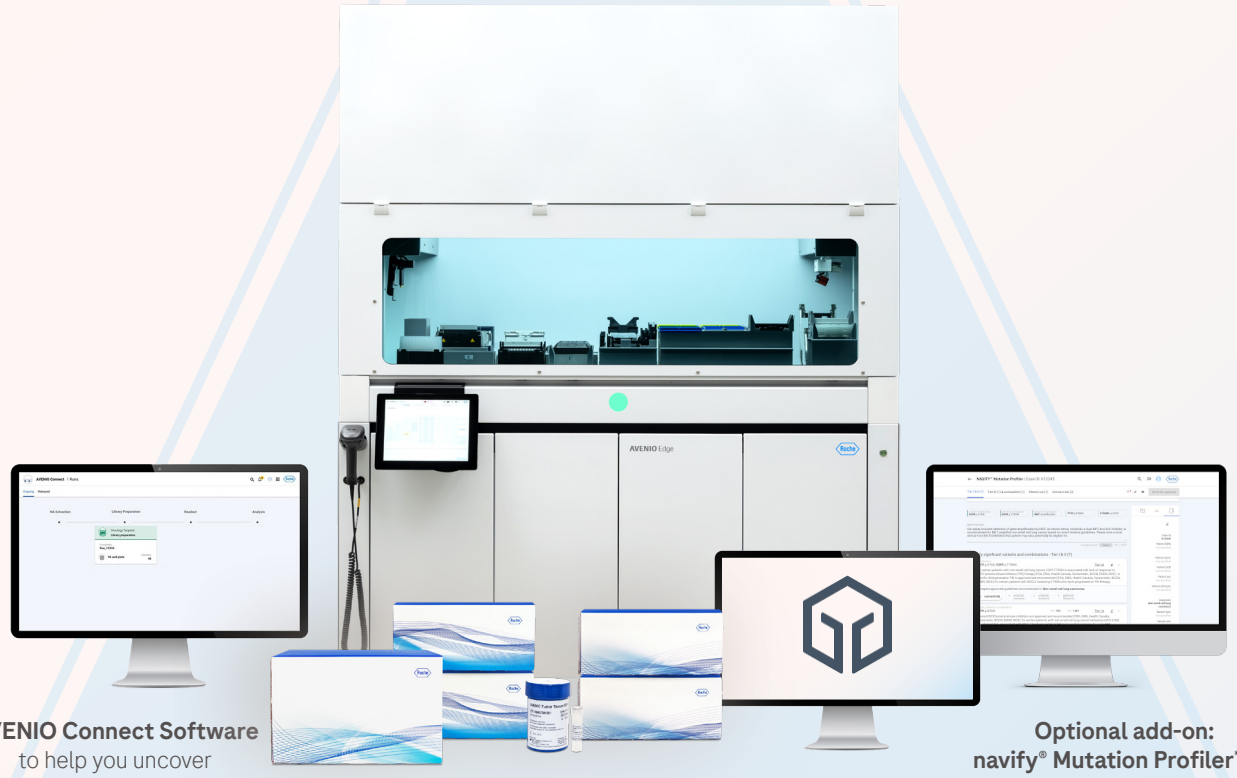
The AVENIO Tumor Tissue CGP Automated Kit: Focus on the breakthroughs, not the process.

The AVENIO Tumor Tissue CGP Automated Kit workflow includes:

True Walkaway Automation

AVENIO Edge System + consumables



AVENIO Connect Software to help you uncover genomic insights by enabling secondary analysis.

High-quality reagents from DNA extraction to library preparation, target enrichment and pooling.

FoundationOne® Analysis Platform for secondary analysis.

Optional add-on: navify® Mutation Profiler*, an oncology decision tool 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.[7]

* navify® Mutation Profiler is CE-IVD in EU. For Research Use Only, not for use in diagnostic procedures in the US and other countries when used with the AVENIO Tumor Tissue CGP Kits.
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.
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Experience **true walkaway automation** and regain time for higher-value tasks.

The AVENIO Edge System is a fully automated system for NGS library preparation, target enrichment, on-deck pooling, normalization, and quantification.[7]

Set up your AVENIO Edge System 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

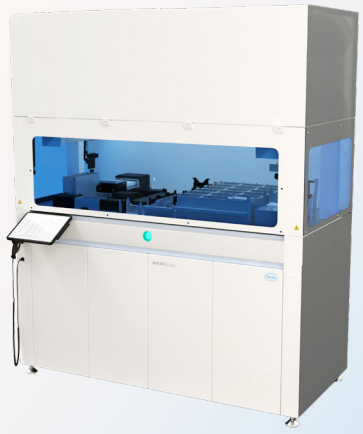
3

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

And leave the system to do the rest

Automation includes:

- **Efficient Installation and Setup**[8]
  Begin installation on Monday, and you can start running CGP samples by Friday.
- **Automation-Ready Reagents**[7]
  Pre-filled kits with barcoded reagents so you don't have to make master mixes prone to the risk of manual pipetting errors.
- **True Walkaway Automation**
  Streamlined, walk-away automation of library preparation, target enrichment, pooling, and normalization with the AVENIO Edge System.
- **Pre-Programmed Roche NGS Workflows**
  We handle the programming for KAPA and AVENIO Tumor Tissue CGP workflows, so you don't have to.
- **Data Integrity**
  User permissions, reagent details, start and stop times, and more are neatly logged and stored in PDF format for easy tracking.



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

Create an end-to-end CGP workflow – from tissue extraction to result generation – with only 3.5 hours of hands-on time.[9]

	Hands-on time	On instrument time	Component
Tissue Digestion & Sample Input Plate Preparation	60 minutes	8 hours (overnight)	DNA Extraction Kit
Automated Library Preparation	60 minutes	24 hours (overnight)	Library and Capture Kit 1, Panel Kit, SID Primer Kit, DNA Quant Kit, Library and Capture Kit 2 (Partial)
Sample Library QC	15 minutes	30 minutes	
Automated Library Pooling	15 minutes	20 minutes	Library and Capture Kit 2 (Partial)
Sequencing Preparation and Sequencing	50 minutes	25 hours	Illumina NovaSeq6000 or Illumina NextSeq 500/550/550Dx (RUO Mode)**
Analysis Submission and Data Retrieval via Connect	10 minutes	12 hours	AVENIO Connect Software and FoundationOne® Analysis Platform
Total hands-on time	**Only 3.5 h of total hands on time within a 5-day workflow.[9]**		

QC - Quality Check
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* When compared to AVENIO Tumor TIssue CGP Kit V2.
** Illumina NovaSeq 6000 and Illumina NextSeq 500/550/550Dx (RUO Mode) instrument and associated sequencing reagents are manufactured and sold by Illumina® and are not sold by Roche.

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.**[10]

Initial Attempt Pass Rate
93.8%[9]
Overall sample pass rate
99.3%[9]

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[10]

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**[11]

High analytical specificity
>99.99% for genomic alterations and signatures

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

Consistent precision with proven lot-to-lot reproducibility[9]

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, actionable reports with ease.

Bring the power of two leaders in oncology, Roche and Foundation Medicine, into your lab.[12,13]

Designed to be comprehensive

ATCGGCA
TTTGGCC
CGCATCG
GACTACG

- Provides genomic information such as **Single Nucleotide Variants (SNVs), Insertions and Deletions (InDels), Copy Number Alterations (CNAs) and DNA-based gene fusion 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).[7,14]
- **Uses a 335-gene panel** that is aligned with the FoundationOne® CDx panel design.[7]
- Enable DNA-based rearrangement/fusion detection with Foundation Medicine's **baitset design**.[15]

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.[14]
- Get access to the most critical, up-to-date, evidence-based information with **navify® Mutation Profiler*** as an add-on.[16]

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.[17]
- **AVENIO Connect Software**, a cloud-based solution, simplifies routine NGS testing workflow. It offers sample tracking and instrument integration through a unified interface, making workflows more efficient, enabling sample audits, and reducing data transfer errors from manual entries.[18]

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The AVENIO Tumor Tissue CGP Automated Kit: Powerful, precise, and proven with >5000 samples[6,10]

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.[7]

Only 3.5 hrs of hands-on time for the end-to-end workflow[9]

Robust Performance

Overcome sample complexity and have confidence in the quality of your results.[6,10]

Overall sample pass rate of 99.3%[9]

Insight Excellence

Get access to an ever-expanding wealth of insights and turn data into actionable information.[12,13]

Growing knowledge and technology of Roche and Foundation Medicine, two leaders in oncology[12,13]

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

References:

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Ordering information (Material Number - Material description):

- 10247177001 - AVENIO Tumor Tissue CGP Automated Kit 1 - 24 rxn
- 10247185001 - AVENIO Tumor Tissue CGP Automated Kit 2 - 24 rxn
- 10247193001 - AVENIO Tumor Tissue CGP Automated Kit 3 - 24 rxn
- 10247207001 - AVENIO Tumor Tissue CGP Automated Kit 4 - 24 rxn

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