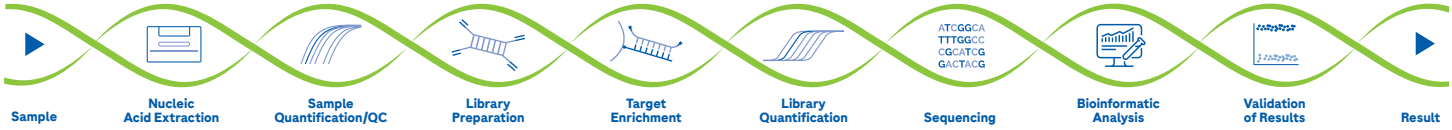
Roche Solutions for Sequencing

Our vision: A future where NGS is simple and accessible enough for routine clinical use



Research Focus

Oncology

Molecular profiling

ctDNA analysis

Hereditary diseases

Genomic biomarkers

Cardiology

Neurology

Infectious diseases

Workflows & Methods

Whole genome sequencing (WGS)

Whole exome sequencing (WES)

RNA sequencing (RNA-seq)

Targeted sequencing (DNA, RNA)

NGS library prep automation

Digital PCR (dPCR) and real-time PCR/qPCR

Automated nucleic acid extraction

Solutions for Sequencing

MagNA Pure 24 System
and
MagNA Pure 96 System
For automated DNA extraction

Page 4

LightCycler® Real-Time PCR Systems
and
KAPA NGS FFPE QC Kit

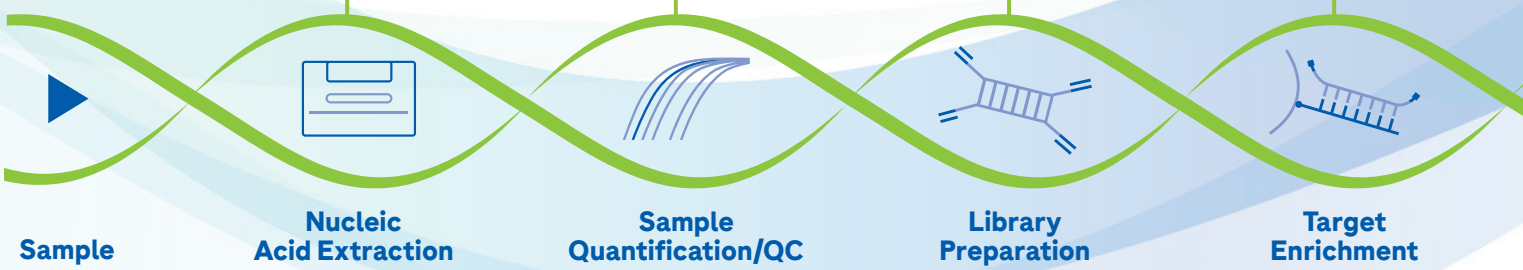
Page 5

KAPA Library Prep Kits, Accessories,
and
KAPA HiFi DNA Polymerase

Pages 6, 7, 8

KAPA Target Enrichment Portfolio
Hybrid-capture and primer extension target enrichment

Pages 9, 10, 11



More Sequencing Solutions

Custom Sample Prep Solutions

Collaborative creation of unique workflows and kits with experts at the Roche Support Network.

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The AVENIO Edge Liquid Handler

An end-to-end IVD liquid handler for NGS library prep and target enrichment.

Pages 14, 15

The MagNA Pure 24 and MagNA Pure 96 Systems, AVENIO Edge Workstation, and the Digital LightCycler® dPCR System are IVD products.
The workflow above shows these products being utilized within a research workflow with other Roche products that are Research Use Only.

KAPA Library Quant Kits
and
LightCycler® Real-Time PCR Systems

Page 12

navify® Mutation Profiler
for tertiary analysis

Page 18

Digital LightCycler® dPCR System
Validate your results (CNVs) via dPCR

Page 19

Library Quantification | **Sequencing** | **Bioinformatic Analysis** | **Validation of Results** | **Result**

AVENIO ctDNA and Tumor Tissue Analysis Kits V2

AVENIO NGS Oncology Assays: an integrated solution that includes reagents, intuitive analysis and reporting.

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AVENIO Tumor Tissue CGP Kit

Integrated end-to-end 5-day workflow solution from DNA extraction through secondary analysis with FoundationOne® Analysis Platform.

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The MagNA Pure 24 and MagNA Pure 96 Systems, AVENIO Edge Workstation, and the Digital LightCycler® dPCR System are IVD products.
The workflow above shows these products being utilized within a research workflow with other Roche products that are Research Use Only.

Because every sample is precious, continued support across the NGS workflow is critical.

Support for the development and validation of seamless workflows *to achieve the sensitivity and precision expected from the world's largest in vitro diagnostics company*

Products designed to work together across the entire NGS workflow*—built upon decades of technology leadership in NGS, target enrichment, and sample prep automation*

A single source for technical expertise for all aspects of library preparation*, from ideation through ongoing support—ensuring reliable, reproducible, high-quality results for assay after assay after assay*

Nucleic Acid Extraction

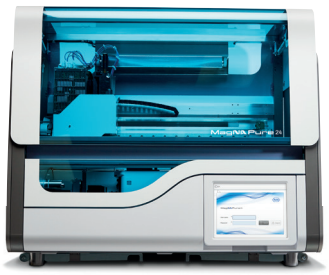
MagNA Pure 24 and MagNA Pure 96 Systems

High-quality starting material increases sequencing success. High-molecular-weight input DNA is essential for the creation of libraries with the 350 – 650 bp inserts required for sequencing whole human genomes on Illumina sequencers.

Obtain high-quality, high-molecular-weight DNA with the **MagNA Pure 24** and **MagNA Pure 96 Systems**. These fully automated nucleic acid extraction instruments provide walkaway automation, require less user intervention, and minimize variability between extractions.

- Reliable DNA extraction from as little as 200 µL whole blood
- Scalable extraction for low, mid, or high throughput
- Optimized protocols for NGS workflows with blood or plasma samples

MagNA Pure 24 System



MagNA Pure 96 System

Table 1. Overview of MagNA Pure System protocols optimized for double-stranded DNA.

Platform	Sample input	Nucleic acids output	Protocol
MagNA Pure 24	blood	genomic DNA	hgDNA ds 200
	plasma	cell-free DNA	cfNA ds 2000
	plasma	cell-free DNA	cfNA ds 4000 hp
MagNA Pure 96	blood	genomic DNA	DNA Blood SV
	plasma	cell-free DNA	cfNA ds 2000
	plasma	cell-free DNA	cfNA ds 4000

Scan to learn more

The MagNA Pure 24 & MagNA Pure 96 Systems are a Class 1 US IVD instruments.

Sample Quantification / QC

Roche LightCycler® 480 System and KAPA NGS FFPE QC Kit

The amount of intact DNA that is used as input into DNA library preparation can have a big impact on the molecular complexity of the resulting libraries; this, in turn, can determine whether the libraries will yield the desired sequencing coverage.

qPCR-based QC of input DNA provides the most accurate assessment of the quality of the input DNA, providing the user with data that enables them to optimize input amounts based on sample quality.

KAPA NGS FFPE QC Kits determine sample quality using two sets of primers that target the human Long Interspersed Nuclear Elements (LINE), which occur across the genome. Amplification with these primers yields a shorter amplicon (66 bp) and longer amplicon (191 bp). The ratio of these two products is used to calculate the Q-score and adjust input amounts, enabling the user to:

- Improve library quality and sequencing coverage from low- or medium-quality samples.
- Assess input quality with greater accuracy compared to assays of individual housekeeping genes.
- Conserve sample when using high-quality samples.

The Roche LightCycler® 480 & LightCycler® PRO Systems ensure reproducible, reliable, accurate data. Leverage the dependable accuracy and temperature homogeneity of the LightCycler® 480 System with KAPA NGS FFPE QC Kits.

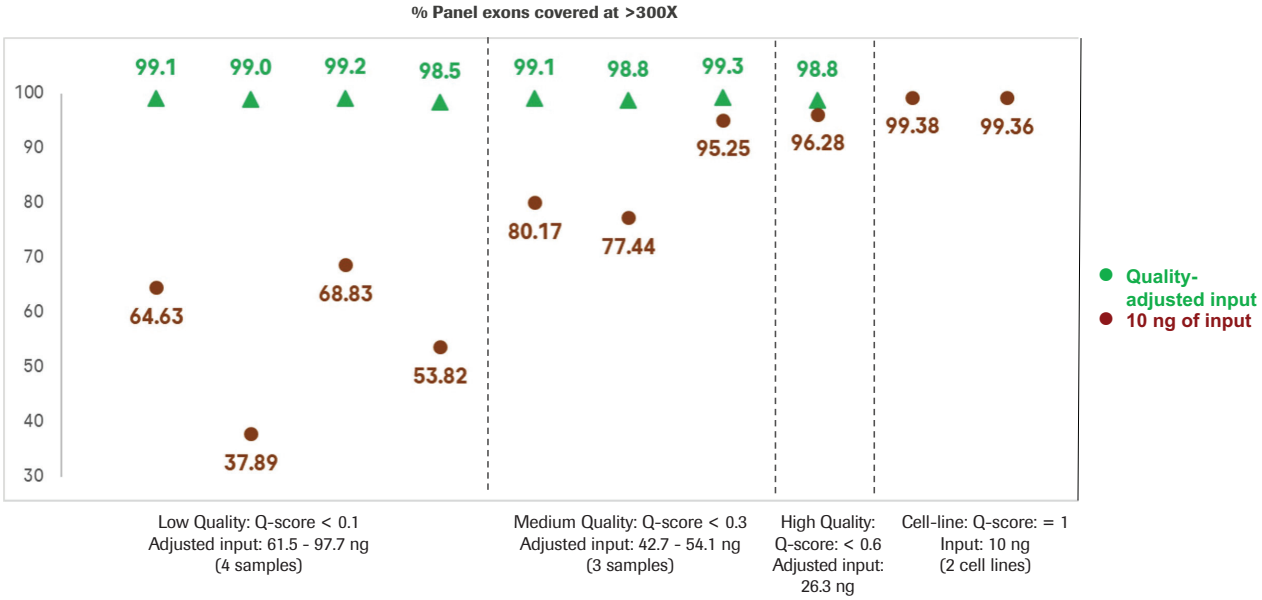


Figure 1. Low-quality, medium-quality, and high-quality input DNA yielded comparable results when quality-adjusted input amounts were used in the KAPA HyperPETE Somatic Tissue DNA Workflow. Designed and supported for the KAPA HyperPETE Somatic Tissue DNA Workflow. Contact US Support & Applications for guidance with other applications and instruments. The quantification/QC study used to determine input amounts was run on the LightCycler® 480.

Scan to learn more

DNA Library Preparation

KAPA DNA Library Preparation Kits

KAPA DNA library prep kits deliver high performance across a diverse array of experimental conditions and sample inputs. Workflows are made simple with sample-conserving, automatable protocols that free up valuable hands-on time while delivering reproducible, high-quality results. Choose from PCR-free or with-PCR formats (including our low-bias, high-fidelity KAPA HiFi DNA Polymerase) for mechanical or enzymatic fragmentation methods.

The new KAPA EvoPrep and KAPA EvoPlus V2 Kits enable you to:

- Achieve higher yields and library conversion efficiency across a range of sample types and DNA inputs (as low as 100 pg);
- Increase efficiency and convenience with automation-friendly ReadyMix reagents and KAPA T4 Ligase, in plated or tube format;
- Rely on consistent performance of kits manufactured to meet the highest quality standards;
- Preserve library diversity with minimal bias for a seamless transition into downstream applications.

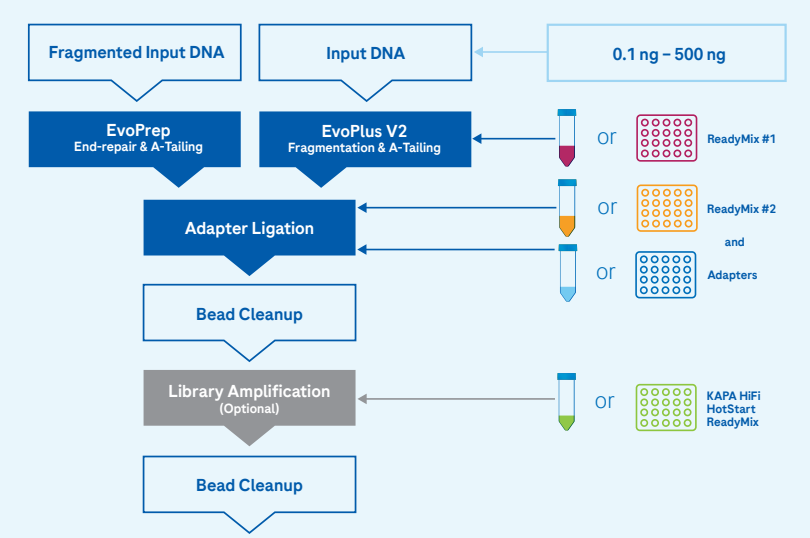


Figure 2. Overview of the newest KAPA DNA library preparation kits, KAPA EvoPrep Kit and KAPA EvoPlus V2 Kit. (KAPA HyperPure beads, KAPA UDI Adapter Kits, and KAPA Library Amplification Primer Mix (10X) or KAPA HyperPlex Adapters sold separately).

Table 2. Comparison of KAPA library preparation kits for DNA.

	Simplify high-performance library prep from mechanically fragmented DNA starting with low inputs.	**Convert** more unique fragments from mechanically fragmented inputs, including low-quality DNA & cfDNA.	**Reduce** workflow complexity with inhibitor-tolerant formulas leading to more consistent results.	**Save time** with a single-tube workflow, for high yields from low-quality inputs such as FFPE.
	KAPA EvoPrep Kits	**KAPA HyperPrep Kits**	**KAPA EvoPlus V2 Kits**	**KAPA HyperPlus Kits**
Fragmentation method	Mechanical	Mechanical	Enzymatic	Enzymatic
Hands-on time	Better	Good	Best	Better
Inhibitor tolerance	Broad tolerance, including EDTA	Robust	Broad tolerance, including EDTA	Low; EDTA-sensitive
Sample input range	0.1 ng – 500 ng	1 ng – 1000 ng	0.1 ng – 500 ng	1 ng – 1000 ng
PCR and PCR-free formats	24, 96, 384 rxn tubes & 96 rxn plates	8, 24, 96 rxn tubes	24, 96, 384 rxn tubes & 96 rxn plates	8, 24, 96 rxn tubes

Scan to learn more

Library Amplification

KAPA HiFi & Library Amplification Kits

KAPA Library Amplification Kits harness the performance benefits of KAPA HiFi DNA Polymerase—a novel enzyme specially formulated to minimize amplification bias while maintaining high fidelity. KAPA Library Amplification Kits can be used with user-supplied primers or with our KAPA Library Amplification Primer Mix, containing primers complementary to Illumina sequencing adapters.

- Improve the detection of true and rare variants with high fidelity.
- Achieve uniform coverage of low-GC/AT-rich regions with low bias.
- Accurately amplify long, complex, and high-GC-content templates with superior processivity.

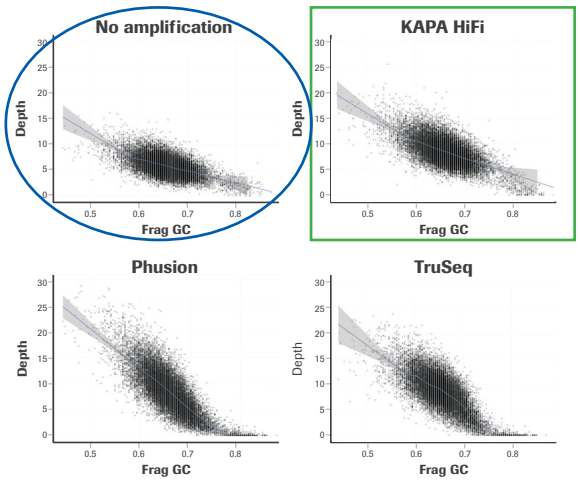
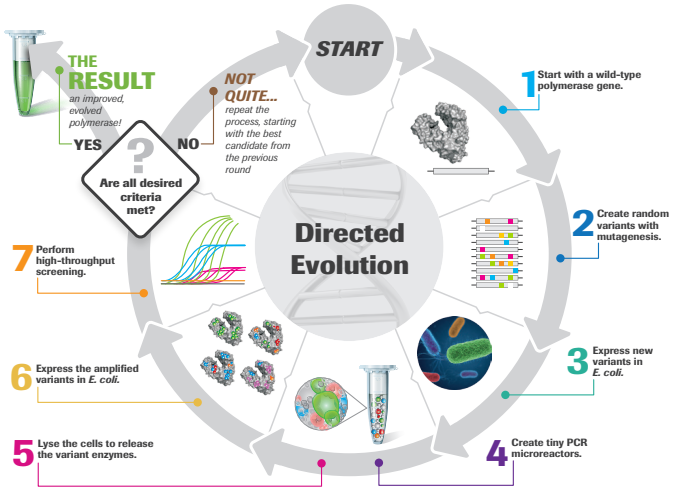


Figure 3. KAPA HiFi HotStart ReadyMix bias is indistinguishable from unamplified libraries. KAPA HiFi is not affected by GC-rich concentration, demonstrating low bias across the range of GC-rich extremes and delivering coverage profiles indistinguishable from unamplified samples **(see highlighted charts above)**.



Typically, choosing a DNA polymerase requires trade-offs between essential performance characteristics such as fidelity or the amplification of long templates, or even settling for compromised performance at application-specific experimental extremes such as inhibitor concentration. KAPA HiFi DNA Polymerase is a product of Directed Evolution—an iterative and highly selective enzyme synthesis process that enables the blending of critical performance parameters and the precise selection of enzymes that deliver uncompromising performance over the full spectrum of experimental conditions.

KAPA Library Amplification Kits and Primer Mixes

KAPA Library Amplification & HiFi ReadyMix Kits
Low-bias production of sequencing-ready libraries.

KAPA Library Amplification Kits with Primer Mix
ReadyMix including primers complimentary to Illumina's p5/p7 flow cell sequences. Specially formulated to limit primer depletion.

KAPA Library Amplification Primer Mix
A primer mix containing sequences complimentary to Illumina P5/P7 flow cell sequences. Available in pre-plated and tube formats.

Scan to learn more

RNA Library Preparation

KAPA RNA HyperPrep Kits

KAPA RNA HyperPrep Kits provide same-day, streamlined workflows for studying gene expression with high-sensitivity and accuracy.

- Generate reliably high-quality results from precious limited and degraded samples.
- Deplete rRNA, globin transcripts, and/or custom-selected RNA targets.
- Automate on a wide variety of liquid handlers **(see page 15)**.

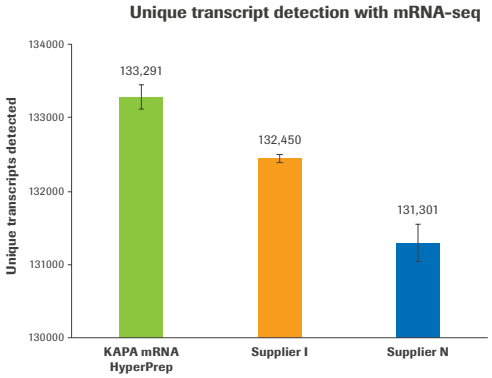


Figure 4. Efficient mRNA capture using KAPA mRNA HyperPrep leads to the detection of more unique transcripts vs. other suppliers. Libraries were generated in quadruplicate using Universal Human Reference (UHR) RNA (Agilent Technologies).

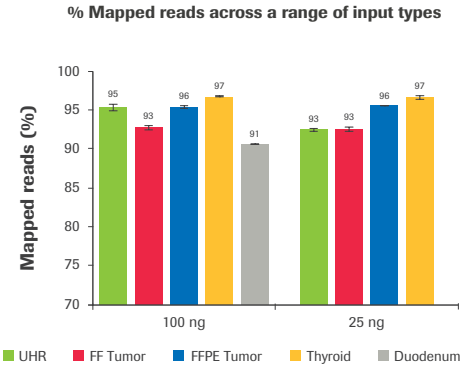


Figure 5. KAPA RNA HyperPrep yields over 90% mapped reads, even with low inputs of FFPET RNA. RNA samples of varying quality were used as input into library construction using KAPA RNA HyperPrep Kit with RiboErase (HMR) with 25 and 100 ng inputs. For highly degraded duodenum FFPE RNA, libraries were only prepared with 100 ng input. All samples were prepared using the standard adapter stock concentration (1.5 µM) and post-ligation cleanup ratios (0.63X/0.7X).

Table 3. Overview of KAPA RNA library preparation kits

	KAPA RNA HyperPrep Kits	KAPA RNA HyperPrep Kits with RiboErase (HMR)	KAPA RNA HyperPrep Kits with RiboErase (HMR) Globin	KAPA mRNA HyperPrep Kits
RNA enrichment	None	rRNA depletion	rRNA and globin depletion	Poly(A) selection
Sample type	▪ High-quality total RNA ▪ Degraded or FFPE total RNA ▪ Previously enriched RNA	▪ High-quality total RNA ▪ Degraded or FFPE total RNA	▪ Blood-derived RNA ▪ High-quality total RNA ▪ Degraded or FFPE total RNA	▪ High-quality total RNA
Species	▪ Eukaryotic (animal, plant, etc.) ▪ Prokaryotic (bacterial, etc.)	▪ Human, mouse, and rat*	▪ Human, mouse, and rat*	▪ Eukaryotic (animal, plant, etc.)
Differentiating applications	Analysis of specific transcripts, including those of low abundance, when paired with target enrichment	Whole transcriptome analysis, including non-coding RNA profiling	Whole transcriptome analysis, including non-coding RNA profiling	mRNA sequencing for coding transcriptome analysis
Shared applications	Gene expression analysis; detection of gene fusions, isoforms, and other structural variants; SNV discovery			
Shared highlights	Streamlined and automation friendly; low duplication rates and high coverage uniformity; single-day workflows including depletion or mRNA enrichment			

*Custom depletion protocol support available for other organisms or transcripts.

Scan to learn more

Target Enrichment

KAPA HyperCap Probes for Hybridization-based Target Enrichment

Better by Design

Combining nearly two decades of probe-design experience with an improved manufacturing process, **KAPA HyperCap Probes** offer fully customizable or pre-designed target enrichment panels for hybridization-based capture in NGS workflows. KAPA HyperCap Probes are manufactured using KAPA HiFi DNA Polymerase and are validated by NGS, resulting in high-quality, expertly designed probes to assist with your most challenging workflows.

Ready-to-ship, **pre-designed KAPA HyperCap Fixed Panels** enable faster access to relevant content, and include KAPA HyperExome V2, KAPA HyperCap Oncology Panel, and KAPA HyperCap Heredity Panel. Additional designs are available from our **KAPA HyperCap Design Share Panel collection**—developed in collaboration with leading researchers around the world—and include panels for hereditary conditions, oncology, and metabolic disease research.

Custom target enrichment panels are easily designed using the **HyperDesign** online software tool (see below). HyperDesign can be used to create either human designs (KAPA HyperChoice Probes) or non-human designs (KAPA HyperExplore Probes).

Combine KAPA HyperCap Probes with KAPA Library Preparation Kits to:

- Reduce sequencing costs and save time with superior capture uniformity.
- Reliably enrich challenging, previously inaccessible genomic regions.
- Streamline your target enrichment workflows, taking advantage of already-developed automated methods on a variety of liquid handlers, including the AVENIO Edge Liquid Handling System by Roche.

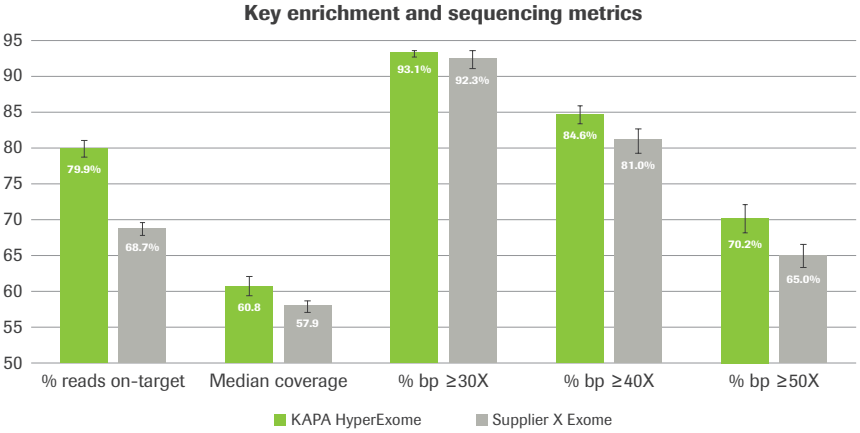


Figure 6. KAPA HyperExome yields greater % reads-on-target, deeper median coverage, and broader target coverage compared to the Supplier X exome. DNA from 16 cell lines was processed in triplicate (48 libraries per workflow); input DNA was enzymatically sheared; samples were pre-capture multiplexed in sets of 8 and hybridized for 16 hours; final post-capture libraries were amplified with 8 PCR cycles; and libraries were sequenced (2 x 100 bp) on an Illumina® NovaSeq™ sequencer. For analysis, sequencing data was subsampled proportionally to exome panel size to achieve the same targeted average depth of coverage.

Reliably enrich challenging, previously inaccessible genomic regions

The user-friendly, online HyperDesign tool builds on two decades of in silico design experience to select probe panels that achieve deeper, more uniform downstream sequencing coverage with fewer sequencing reads—even across difficult-to-capture regions.

HyperDesign

Design your new probe panel in 4 easy steps:

1. Visit **www.HyperDesign.com** and select your organism of interest.
2. Add your targets by uploading gene names, bed files, or genomic coordinates—or choose from a broad list of commonly used gene identifiers.
3. Fine-tune your inputs, review your targets, and confirm your results.
4. Submit your design for probe selection.

Scan to learn more

Target Enrichment

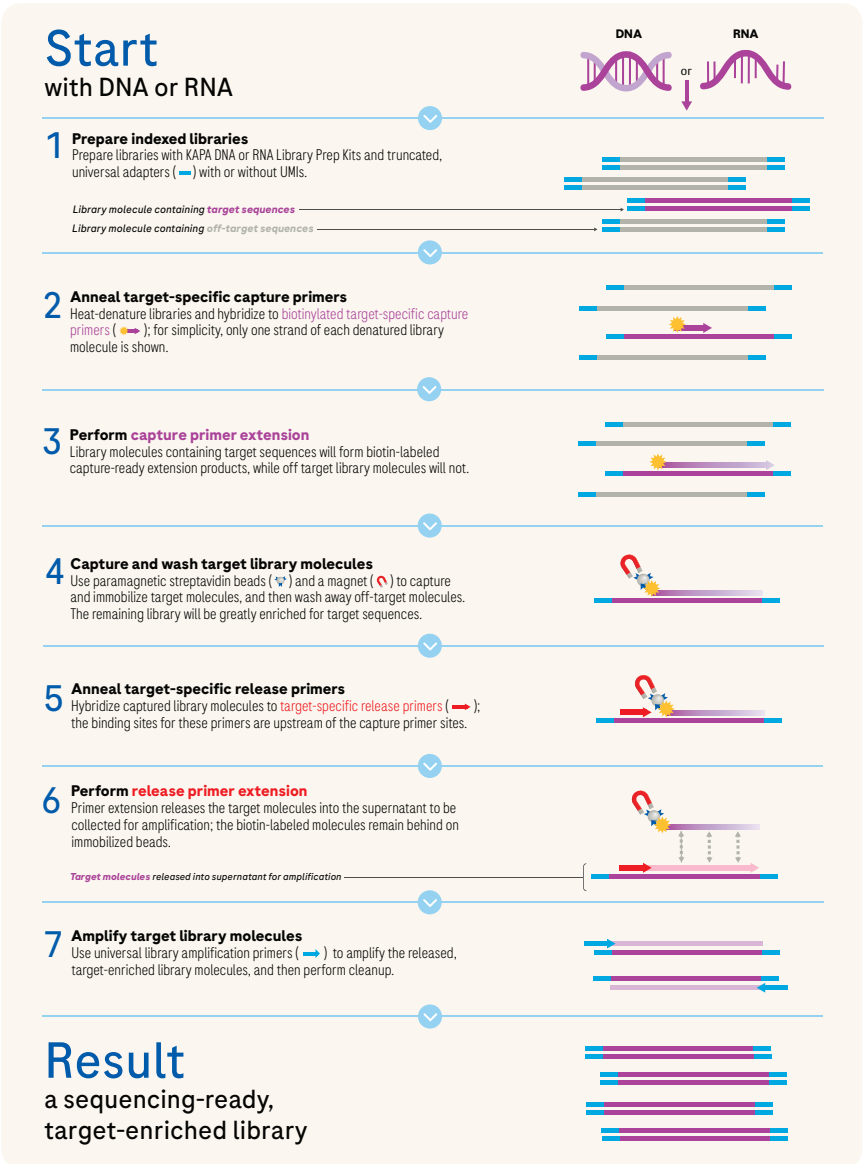
What is Primer Extension Target Enrichment (PETE)?

KAPA HyperPETE is a novel NGS hybridization capture technology designed to employ primer extension reactions to specifically capture and release target library molecules for sequencing.

What's different about PETE?

Other target enrichment technologies offer either uniform, high-quality data (via probe hybridization) or fast, simple workflows (via amplicon-based enrichment). PETE brings together the benefits of both workflows—combining speed and simplicity with deep, uniform, high-quality coverage.

Here's how KAPA HyperPETE works...



Perform fewer manual steps

Save valuable time

Achieve superior performance

The **single-day KAPA HyperPETE workflow** can detect all major somatic variant types—including SNVs, short indels, CNVs, MSI, and fusion transcripts—from a wide variety of sample types, including degraded DNA and RNA. To learn more about PETE technology and Roche's KAPA HyperPETE portfolio, visit **go.roche.com/KAPAHyperPETE**.

Scan to learn more

Target Enrichment

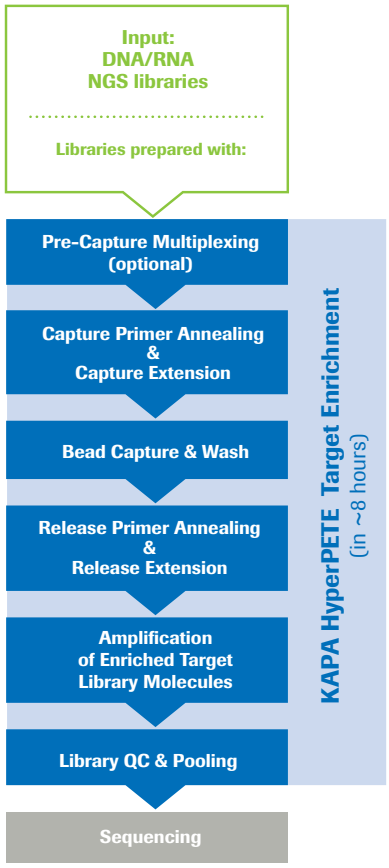
KAPA HyperPETE Primers for Primer-Extension Target Enrichment

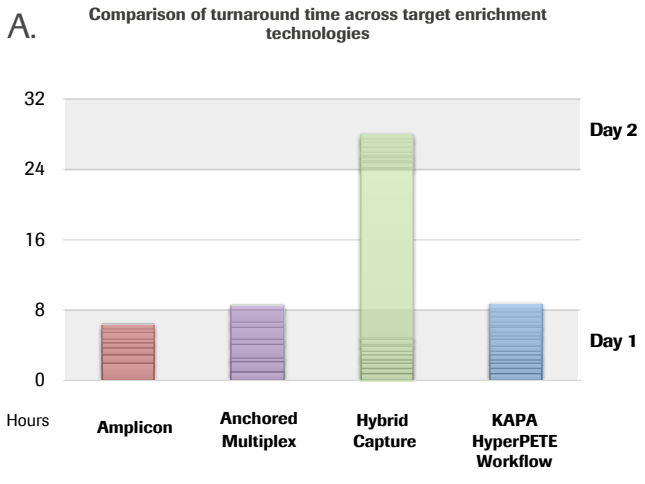
Combine the performance of hybrid-capture target enrichment with the speed and simplicity of amplicon workflows.

KAPA HyperPETE is a novel hybrid-capture technology designed to employ primer extension reactions to specifically capture and release target library molecules for sequencing. It is designed and optimized to detect all major somatic variant types, including SNVs, short indels, CNVs, MSI, and fusion transcripts (known and novel). KAPA HyperPETE is compatible with a wide variety of sample types, including challenging samples—such as cfDNA and FFPET-derived DNA and RNA.

The KAPA HyperPETE Portfolio includes readily available fixed-design panels for hereditary oncology, oncology hotspots, lung cancer fusion variants, and pan-cancer variants (with an MSI module). In addition, custom panels can be designed using **HyperDesign**, our easy-to-use online design tool.

- Save valuable time with an efficient, single-day (~8 hours), automation-friendly workflow.
- Achieve superior performance and coverage uniformity.
- Uncover critical genomic information from a wide variety of sample types, including FFPET and cfDNA.
- Take hours off of total workflow time compared to typical hybridization capture, with time requirements similar to amplicon and anchored multiplex methods **(Figure 7)**.
- Enrich for long contiguous regions, using fewer tubes per sample compared to amplicon workflows.





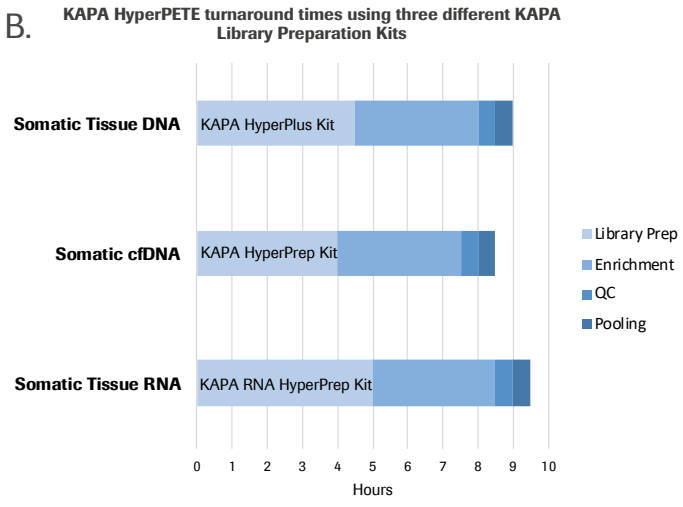


Figure 7. The turnaround time (TAT) for KAPA HyperPETE target enrichment is similar to the TAT for amplicon-based workflows. (A) While most hybridization-based workflows take two days to complete, KAPA HyperPETE workflows can be completed in one day. **(B)** Differences in the TAT for various applications of KAPA HyperPETE are dependent on the library preparation kit used, as each kit requires slightly different completion times. However, once the libraries are created, the enrichment workflow is the same across applications.

Scan to learn more

Library Quantification

KAPA Library Quantification Kits and Roche LightCycler® Systems

Sequencing capacity is maximized when sequencing-competent molecules are accurately measured with qPCR, enabling libraries to be pooled at the desired ratios.

Clustering can be optimized by quantification of library pools, further improving sequencing results.

Roche LightCycler® 96 Instrument, LightCycler® 480 System, and LightCycler® PRO System ensure reproducible, reliable, accurate data.

- Scalable instrument options
- Dependable temperature accuracy and homogeneity
- Ideal for use with KAPA Library Quantification Kits

KAPA Library Quantification Kits, which are referenced in thousands of scientific publications, contain all reagents needed for qPCR-based quantification of NGS libraries for Illumina® sequencing.

- Accurately quantify sequencing-competent libraries **(Figure 8)**.
- Pool libraries with better accuracy for more balanced multiplexing.
- Automate KAPA Library Quantification Kits for increased throughput **(see page 15)**.

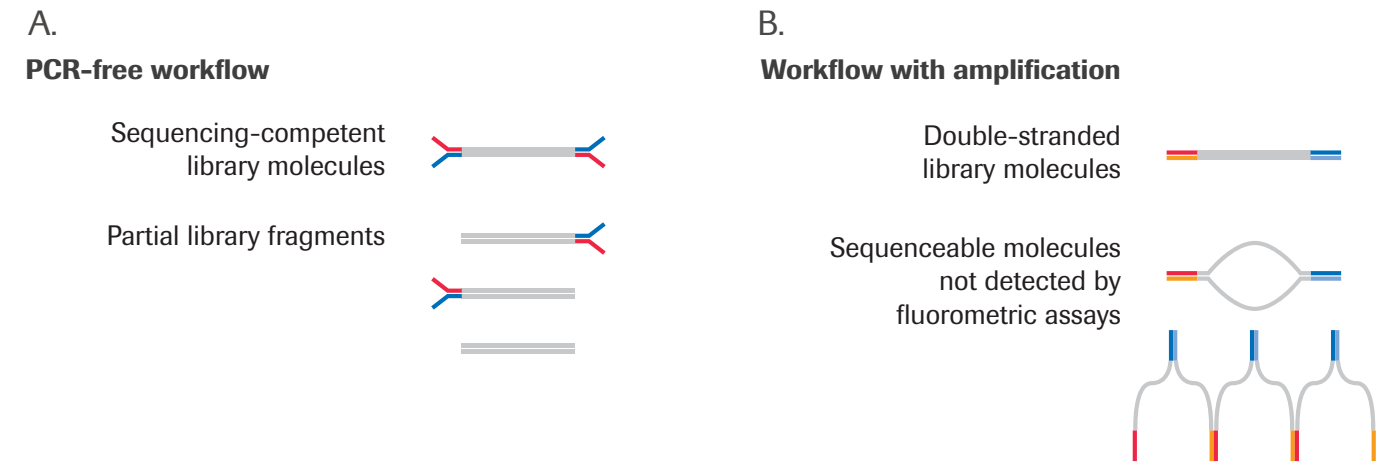


Figure 8. Library quantification via qPCR-based methods, such as the KAPA Library Quantification Kit, enables accurate sample pooling and optimal clustering.

(A) Libraries prepared with PCR-free workflows can contain partial library fragments that are not sequenceable. qPCR-based library quantification methods detect only the sequencing-competent molecules. In contrast, other assays detect fragments that are not sequenceable, leading to *underclustering* on the sequencing flow cell.

(B) Libraries prepared using methods with PCR amplification can include sequencing-competent single-stranded configurations. qPCR-based library quantification data counts these molecules. In contrast, other methods do not detect these molecules, leading to *overclustering* on the sequencing flow cell.

Scan to learn more

Custom Sample Prep Solutions

Unique kits designed for your unique workflows

Created with the same high-quality **KAPA library prep reagents** in combinations that help you maximize efficiency, increase throughput, and reduce costs.

Flexibility where you need it…

Unique buffer and enzyme combinations *to maximize efficiency and fit your workflow*

Adapted for the throughput of your lab…

Custom fill volumes and reagent sizes *to help minimize waste and achieve the scale you need*

With customized packaging...

Made-to-order packaging and labeling *to meet your unique specifications*

Contact us to discuss your unique needs for:

Library Preparation

Target Enrichment

Sample Quantification/QC

Automation

Collaborative creation of robust workflows with experts at the Roche Support Network

Scan to learn more

NGS Sample Prep Automation

The AVENIO Edge Liquid Handling System for end-to-end library prep and target enrichment

Automate your low- to medium-throughput NGS library preps with as little as 20 minutes of hands-on time and no prior NGS or automation experience.

Freedom to walk away with confidence and trust in the results

AVENIO Edge Liquid Handling System is Roche's fully automated solution for NGS library preparation, including target enrichment and library normalization and pooling. It is designed to greatly reduce the complexity of automation for users at any level, and provide a true walk-away experience.

As little as 20 minutes of set up time for each run

On-deck thermocycling and quantification module

Cartridge-based and ready-to-use reagents

Intuitive software and a built-in controller PC

Remote access connectivity to enable real-time troubleshooting

Glove-compatible touchscreen

Easily run your whole exome or smaller cancer research panels on the **AVENIO Edge Liquid Handling System** with as little as 20 min hands-on time for end-to-end library prep and target enrichment.

Examples:

- KAPA HyperExome V2 Probes
- KAPA HyperCap Non-Hodgkin Lymphoma (NHL) Panel
- KAPA HyperCap Oncology Panel

For more information about the AVENIO Edge Liquid Handling System, contact your Roche sales representative or visit: **sequencing.roche.com/AVENIOEdge**

Scan to learn more

Automated KAPA NGS Library Prep Workflows

On non-Roche liquid handlers

Roche's NGS Automation Support Team, in collaboration with non-Roche liquid handling vendors, creates menus of automated methods for KAPA library prep reagents.

Let's talk about the next steps to get you up and running with automating your NGS library prep protocols.

Scan the QR code below or fill out the Contact Us form at **go.roche.com/AutomationSupport**.

Table 4. Automated NGS library preparation workflows supported by Roche.

Vendor and Platform		DNA Library Preparation				RNA Library Preparation					Quant and QC	Target Enrichment	Oncology
Vendor	Platform	KAPA HyperPrep	KAPA HyperPlus	KAPA EvoPlus		KAPA Stranded RNA-seq	KAPA Total RNA HyperPrep	KAPA mRNA HyperPrep	KAPA RNA HyperPrep RiboErase +Globin	KAPA Shortened RNA HyperPrep RiboErase +Globin	KAPA Library Quant	KAPA HyperCap v3	AVENIO ctDNA
				Tubes	Plates								
Agilent	Bravo NGS	✓	✓			✓					✓		
	Bravo NGS Workstation	✓	✓			✓	✓	✓	✓	✓	✓	✓	
Beckman Coulter Life Sciences	Biomek FX^P Hybrid Workstation	✓	✓			✓	✓	✓	✓		✓	✓	✓
	Biomek i7 Hybrid Workstation	✓	✓	✓	✓		D	✓	✓	✓	✓	✓	
	Biomek i5 MC Workstation	✓	✓		✓								
	Biomek i5 Span-8 Workstation	✓	✓										
Eppendorf	epMotion® 5075t	✓	✓			✓	✓	✓	✓		✓	D	
Hamilton	NGS STAR (8-channel)	✓	✓					✓	✓		✓	✓	
	NGS STAR MOA	✓	✓	D									
	NGS STAR V				✓								
Revvity	Sciclone G3 NGSx Workstation	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
	Sciclone G3 NGSx IQ Workstation	✓	✓									✓	
	Zephyr G3 NGS Workstation	✓	✓			✓	✓	✓	✓		✓		
SPT Labtech	firefly®				✓						✓		
Tecan	DreamPrep® NGS	✓	✓										
	Freedom EVO® NGS Platform	✓	✓				✓	✓	✓				

✓ = Complete and in distribution (Roche) D = In development (Roche) ✓ = Complete and in distribution (Vendor) D = In development (Vendor)

Agilent · Beckman Coulter Life Sciences · eppendorf · HAMILTON · revvity · sptlabtech · TECAN.

Scan to learn more

AVENIO ctDNA & Tumor Tissue Analysis Kits V2

A versatile solution for multiple research applications

Comprising three liquid biopsy assays and three corresponding tumor tissue assays with exactly matched panels, the AVENIO NGS Oncology Assays offer a uniquely versatile solution for tumor profiling, monitoring, and concordance analysis.

Innovative panel design and workflow

The AVENIO assays include three kits for the analysis of circulating tumor DNA (ctDNA) and three kits for analyzing tumor tissue. Each panel in the Targeted, Expanded, and Surveillance kits includes biomarkers in the U.S. National Comprehensive Cancer Network (NCCN) Guidelines.

Analytical concordance

AVENIO kits are built for versatility, providing the ability to switch between tissue and plasma to support a variety of potential research applications. The analytical concordance feature in the AVENIO Oncology Analysis Software enables a simple yet detailed comparison of results across any two samples.

Targeted Kits

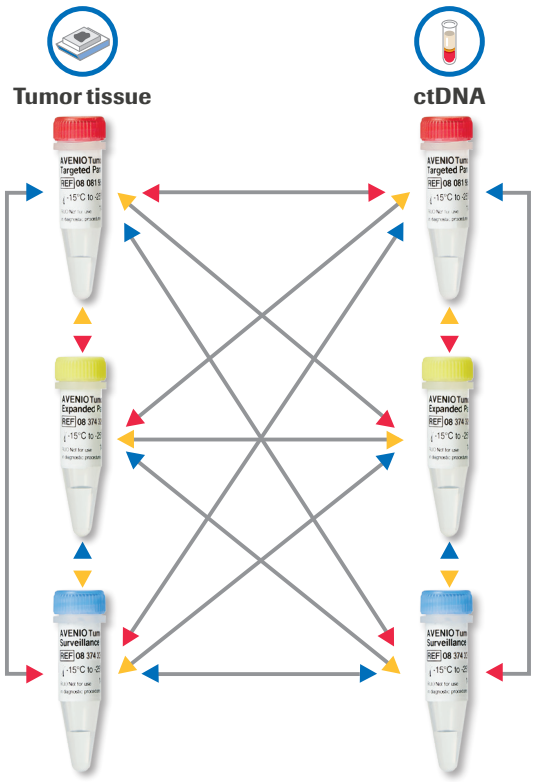
17 genes **81 kb**	17 guideline-aligned genes for genomic profiling of solid tumors

Expanded Kits

77 genes **192 kb**	17 guideline-aligned genes and 60 emerging biomarkers investigated in clinical research for expanded profiling of solid tumors

Surveillance Kits

197 genes **198 kb**	17 guideline-aligned genes, plus 471 frequently mutated disease-associated regions across 197 genes; optimized for longitudinal monitoring of tumor burden in lung and colorectal cancer



Exactly matched panels in corresponding ctDNA and tissue kits, as well as the inclusion of the same 17 guideline-aligned genes in all AVENIO assays, facilitate concordance analysis.

AVENIO assays accurately and reliably identify alterations in genes known to be somatically altered in cancer. These genes are sequenced at great depth to identify the relevant somatic alterations, including SNVs, indels, CNVs, and fusions.

Scan to learn more

AVENIO Tumor Tissue CGP Kit

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

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

FOUNDATION MEDICINE® | Roche

Designed to match the content of the 324-gene FoundationOne® CDx panel, the **AVENIO Tumor Tissue CGP Kit** enables labs to implement in-house comprehensive genomic profiling with an integrated end-to-end 5-day workflow solution from DNA extraction through secondary analysis with FoundationOne® Analysis Platform.

From DNA isolation to secondary analysis in 5 days

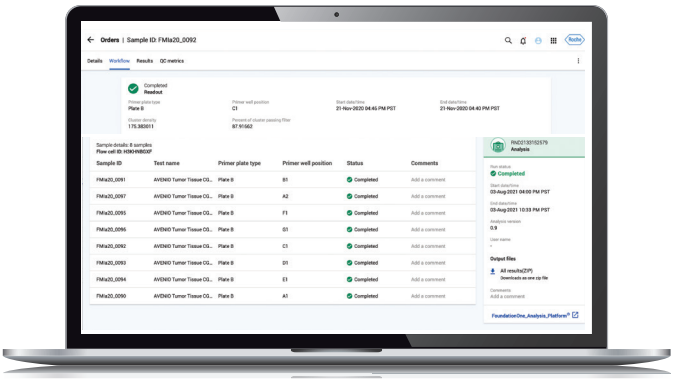
Detects 4 genomic alterations (InDels, Rearrangements, CNAs and SNVs)

Assesses 3 complex genomic signatures (TMB, MSI and LOH)

Integrated end-to-end workflow solution

FoundationOne® Analysis Platform

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



- Evidence-driven variant calling knowledge base for secondary analysis, built on unique insights from FMI's experience in profiling over 500,000+ samples
- Continuously evolving based on evidence compiled by a multidisciplinary team of cancer biologists from scientific publications, conferences, and online databases (COSMIC, dbSNP, gnomAD, 1000 Genomes)
- Web application for download of analysis output files (VCF, JSON, CSV, BAM)

Roche offers an extensive CGP portfolio that includes the AVENIO Tumor Tissue CGP Kit and navify® Mutation Profiler software for tertiary analysis.

CGP, comprehensive genomic profiling. Indels, insertion deletion. CNAs, copy number alterations. SNVs, signal nucleotide variants. TMB, tumor mutational burden. MSI, microsatellite instability. LOH, genomic loss of heterozygosity.

Scan to learn more

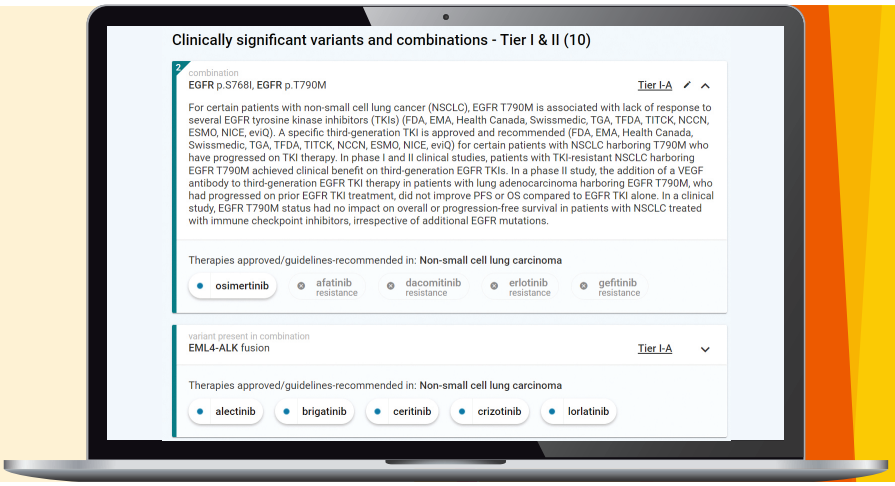
Bioinformatic Analysis

Cloud-based secondary and tertiary analysis solutions

navify® Mutation Profiler

Cloud-based tertiary analysis for NGS assay or platform

Streamline your interpretation, annotation and reporting of oncology sequencing data with an intuitive interface and the comprehensive Roche knowledge base—with access to targeted therapies and clinical trials—for personalized medicine studies.



navify® Mutation Profiler

- Reduces time-to-report with its easy-to-use interface
- Secured - ISO, HIPAA, and GDPR-EU compliant system
- Enables shared lab analytics and variant classification
- Option to share and access anonymized data to aid in analysis
- Customizable content & reports
- Integrates with institutional information systems

The Roche knowledge base:

- Provides in-depth, up-to-date content for Genomic LOH, TMB, and MSI
- Offers access to clinical trial information for >140 countries
- Informs on implications of variant combinations for characterizing disease
- Undergoes a rigorous, multi-step data-quality curation process

Roche offers an extensive CGP portfolio of flexible solutions which includes navify Mutation Profiler software and the AVENIO Tumor Tissue CGP Kit for in-house comprehensive genomic profiling.

AVENIO Tumor Tissue CGP Kit and navify Mutation Profiler are for Research Use Only. Not for use in diagnostic procedures.
AVENIO and NAVIFY are registered trademarks of Roche.
ISO, International Organization for Standardization. CGP, comprehensive genomic profiling. HIPAA, Health Insurance Portability and Accountability Act. GDPR-EU, General Data Protection Regulation European Union. LOH, genomic Loss of Heterozygosity. TMB, Tumor Mutational Burden. MSI, Microsatellite Instability.

navify®

Validation of Sequencing Results

The Digital LightCycler® dPCR System

The Digital LightCycler® dPCR System combines sensitivity, precision, flexibility, and integration in one powerful clinical research tool. This can be used to validate variants revealed by NGS—including investigating minimal residual disease (MRD)—and much more.

This system has the potential to advance global medical knowledge by enabling researchers and physicians to push beyond the current boundaries of clinical research.

The unique combination changing the future of digital PCR

3

3 nanowell plate configurations:

- 20,000-partition High-Sensitivity Plate (45 µl)
- 28,000-partition Universal Plate (30 µl)
- 100,000-partition High-Resolution Plate (15 µl)

6

6 advanced optical channels:

- Enable a high degree of multiplexing
- A separate channel for controls

5

5X concentrated master mixes:

- 4:1 sample:master mix ratio enables more DNA or RNA sample per reaction

The Digital LightCycler® dPCR System elevates clinical research

Sensitivity

- Detect indels down to <0.2% allele fraction with the 20,000-partition plate.
- Detect rare mutations down to <0.1% allele fraction with the 28,000-partition plate.

Precision

- Discriminate small differences between samples with the 100,000-partition plate.
- Obtain high-resolution results for absolute quantification with short turnaround times, accelerating publication and the development of clinically viable assays.
- Minimize the risk of amplicon contamination by virtue of the Digital LightCycler's® closed system.

Flexibility

- Address multiple challenges at once with 6 optical channels and 3 plate configurations.
- Increase resolution by running a single sample on multiple lanes and combining results.
- Choose batch size increments of between 8 and 96 samples per run.

Integration

- Integrate unique Digital LightCycler® features within a closed system to minimize contamination.
- Simplify your workflow with sample tracking through LIMS connectivity and automated data analysis.

Scan to learn more

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