

Genomic Profiling for Clinical Development of Precision Medicine

Comprehensive Genomic Sequencing to Identify Somatic Alterations in Solid Tumors

Introducing **PanCancerIQ™**, our next-generation sequencing (NGS) service that enables comprehensive genomic profiling of tumor samples.

The Eurofins Viracor new **PanCancerIQ™** service uses the Illumina TruSight Oncology 500 (TSO500) assay system, combined with clinical interpretation through utilization of a knowledgebase developed by MD Anderson Cancer Center via a partnership with Philips.



PanCancerIQ supports identification of the four main classes of alterations known to drive cancer growth: mutations, insertions and deletions (indels), copy number variations (CNV), and gene fusions.

In addition, the assay accurately measures key current immuno-oncology biomarkers: microsatellite instability (MSI) and tumor mutational burden (TMB).

The assay also identifies oncogenic driver events that predict response or resistance to treatments, enabling the rapid confirmation and validation of clinically relevant mutations, helping clients accelerate their clinical development.

Now you can interrogate the oncogenome with unparalleled breadth and sensitivity, using our integrated genomic solutions along with many other complementary cell-based assay services to accelerate your oncology research and drug development programs.

Complete Genomic Sequencing Solution with Comprehensive Analytics

- Expertise in interrogating FFPE samples
- Optimal sensitivity and reproducibility
- Improved limits of detection and coverage depth
- Accurate and sensitive detection of disease-related, and therapy relevant genomic alterations
- Bioinformatics expertise for custom analysis and clinical interpretation
- CAP/CLIA validated assay

Genomic Profiling for Clinical Development of Precision Medicine

TSO500 is a hybrid capture-based approach targeting 523 oncology-relevant genes, including biomarkers that are both FDA-approved and in the NCCN guidelines.



The assay leverages unique molecular indices to enable accurate, ultra-low frequency detection of SNVs and Indels. This comprehensive cancer panel interrogates relevant cancer biomarkers with as little as 40 ng of DNA and 20 ng RNA, demonstrating robust analytical performance. In addition to variant calls, the assay reports a tumor mutational burden (TMB) score and microsatellite instability (MSI) status.

PanCancerIQ™ Specifications

Description and Sample Requirements:

FFPE (DNA and RNA)
523 genes for DNA variants
55 genes for RNA variants

Variants called:

SNVs
InDels
CNVs
Fusion
Splice Variants
IO signatures (TMB, MSI)

Panel size:

1.94 Mb DNA; 358 kb RNA

Sample input:

40 ng DNA
20 ng RNA

FFPE Sections:

5 µm, min 20% cellularity, <20% necrosis
FFPE slides
10-20 slides

Our expertise in targeted FFPE sequencing, combined with an industry leading NGS platform and high value bioinformatics analysis, provides the ability to rapidly confirm and validate study relevant mutations to accelerate clinical research on novel anti-cancer therapeutics.

PanCancerIQ™ Performance

Whole panel CAP/CLIA validated for FFPE

Sensitivity:	
VAF limit of detection (LOD):	As low as 1% for $\geq 1000X$ coverage
Analytical Sensitivity (LOD):	Minimum DNA for TMB, MSI, CNV: 20 ng
	Minimum DNA for SNVs, Indels: 40 ng
	Minimum RNA: 20 ng
Analytical Specificity:	
Accuracy:	PPA $\geq 98\%$; PPV $\geq 95\%$
	TMB: 85% - 99% (sample dependent)
	MSI: 96% - 99%
	CNV: PPA $\geq 90\%$
	RNA: PPA $\geq 90\%$
Precision:	Small variants: PPA $> 95\%$
	MSI, TMB: %CV $< 30\%$ or St Dev < 4
	Structural variants: PPA $> 95\%$

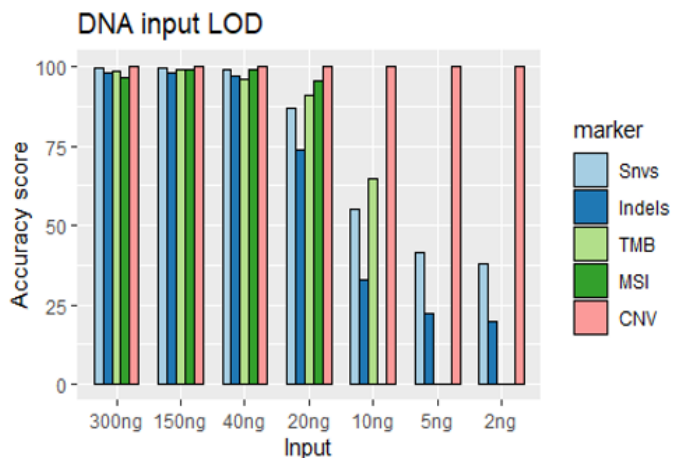
Driven by science, the innovative, consultative approach of our BioPharma team enables clients to overcome obstacles and get faster results. Our new PanCancerIQ assay can help:

- Effectively identify relevant alterations
- Maximize genomic data from limited samples
- Screen patients for enrollment
- Stratify patient cohorts
- Provide biomarker-driven trial optimization
- Optimize clinical trial design and development decisions
- Assess the efficacy of targeted anticancer therapies
- Accelerate the implementation of precision oncology and guide the better use of targeted drugs

Eurofins Viracor BioPharma Advantage:

- Broad biomarker panel (Variants, Indels, CNV, Fusions, TMB, MSI)
- CAP-CLIA-validated assay for rapid and accurate genetic analysis of FFPE tissue
- Improved limits of detection and coverage depth
- In-house NGS and Bioinformatics expertise for analysis, interpretation, and biomarker assay development
- Extensive global testing network

High Sensitivity and Accuracy of DNA Variants



DNA Limit of Detection: 40 ng for SNVs & indels, 20 ng for CNVs, TMB & MSI

OncoSpan is a well-characterized, cell line-derived Reference Standard containing 386 variants across 152 key cancer genes.

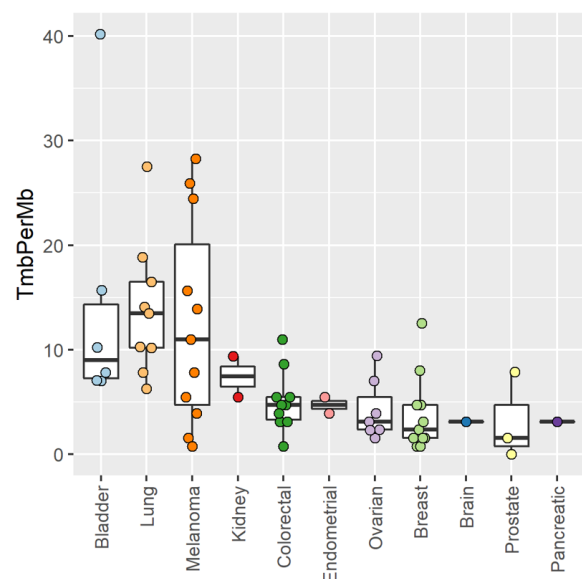
Sensitive and Accurate RNA Fusion Detection:

SeraCare RNA Fusion mix V4				
Fusion	80ng	40ng	20ng	10ng
CCDC6-RET	✓	✓	✓	✗
CD74-ROS1	✓	✓	✓	✗
EGFR variant III	✓	✓	✓	✗
EGFR-SEPT14	✓	✓	✓	✗
EML4-ALK	✓	✓	✓	✗
ETV6-NTRK3	✓	✓	✓	✓
FGFR3-BAIAP2L1	✓	✓	✓	✓
FGFR3-TACC3	✓	✓	✓	✓
KIF5B-RET	✓	✓	✓	✓
LMNA-NTRK1	✓	✓	✓	✓
MET Exon 14 Skipping	✓	✓	✓	✗
NCOA4-RET	✓	✓	✓	✓
PAX8-PPARG1	✓	✓	✓	✓
SLC34A2-ROS1	✓	✓	✓	✗
SLC45A3-BRAF	✓	✓	✓	✓
TFG-NTRK1	✓	✓	✓	✓
TMPRSS2-ERG	✓	✓	✓	✓
TMP-NTRK1	✓	✓	✓	✓

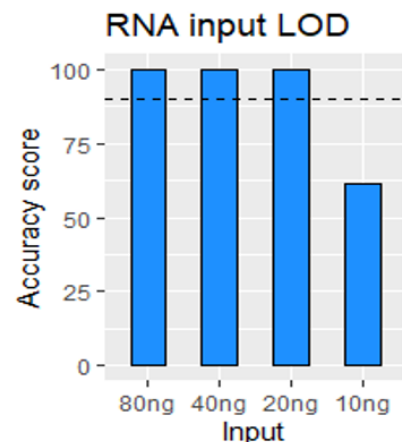
Custom Bioinformatics Services

- Clinical interpretation
- Time-to-event analysis
- Predictive modeling and classification
- Data linkage to clinical endpoints
- Mutational signature analysis
- Pathway analysis
- Open source and proprietary algorithm development

Analysis of TMB in multiple cancer types:



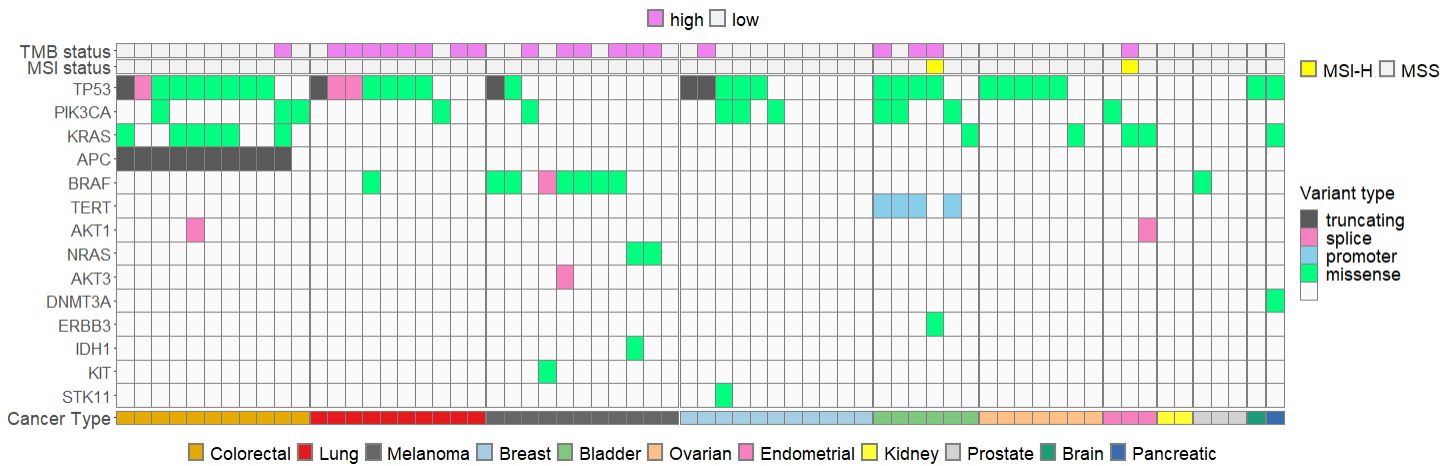
Seracare RNA mix V4 Reference (RNA Reference Standard with 18 clinically relevant RNA fusions)



Genomic Profiling for Clinical Development of Precision Medicine

PanCancerIQ Clinical Data Overview:

Oncoplot of the Top Mutated Genes from 66 clinical samples across 11 different indications



Mutations identified in clinical specimens confirmed by external lab genomic panel:

- Top 25 mutated genes with clinical significance showed 98% concordance
- 94% concordance across SNV, Indels, and structural variants
- >95% concordance across overlapping copy number alterations

Standard PanCancerIQ™ Data Deliverables

- Sample QC metrics
- Sequencing QC metrics report
- VCF files
- Combined variant report (TMB, MSI, CNV, fusions, splice variants, small indels)
- Fastq and BAM files available upon request

PanCancerIQ™ Data Interpretation

- The panel will be interpreted using Philips IntelliSpace interface powered by MD Anderson Cancer Center knowledgebase PODS.
- Additional clinical support will be provided by all cases with multiple actionable findings using CureMatch Bionov software

Let our experts support your biomarker-driven clinical trial programs with the comprehensive NGS solution that offers proven utility, combined with our other complementary capabilities (flow cytometry, ddPCR), for a more complete assessment.

Eurofins Viracor BioPharma offers an extensive array of genomic services to support translational research, and clinical development of precision medicine.

Contact us today to discover how the Viracor Eurofins team can make the difference in your projects.

Viracor Eurofins Biopharma Services
1001 NW Technology Dr.
Lee's Summit, MO 64086 USA
clinicaltrials@viracor-eurofins.com
Tel +1 800 305 5198
Fax +1 816 347 0143
www.eurofins-viracor.com/biopharma