eurofins | Clinical Trial Solutions

Genomic Profiling for Clinical Development of Precision Medicine

Comprehensive Genomic Sequencing to Identify Somatic Alterations in Solid Tumor Biopsies

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

The Eurofins Clinical Trial Solutions 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 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
- Accurate and sensitive detection of disease-related, and therapy relevant genomic alterations
- Bioinformatics expertise for custom analysis and clinical interpretation
- CAP/CLIA validated assay

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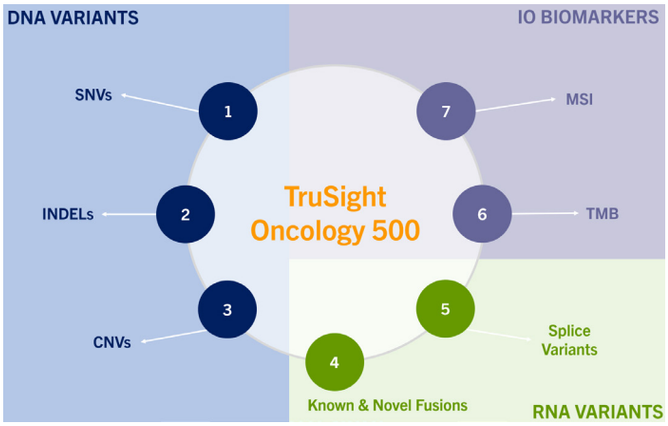
TSO500 is a hybrid capture-based approach targeting 523 oncology-relevant genes, including biomarkers that are both FDA-approved and in the NCCN guidelines.



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 um, 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 >= 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 >=98%; PPV >=95%
	TMB: 85% - 99% (sample dependent)
	MSI: 96% - 99%
	CNV: PPA >=90%
	RNA: PPA >=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 Clinical Trial Solutions team enables clients to overcome obstacles and get faster results. Our new **PanCancerIQ™** assay can help:

- 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

Genomic Profiling for Clinical Development of Precision Medicine

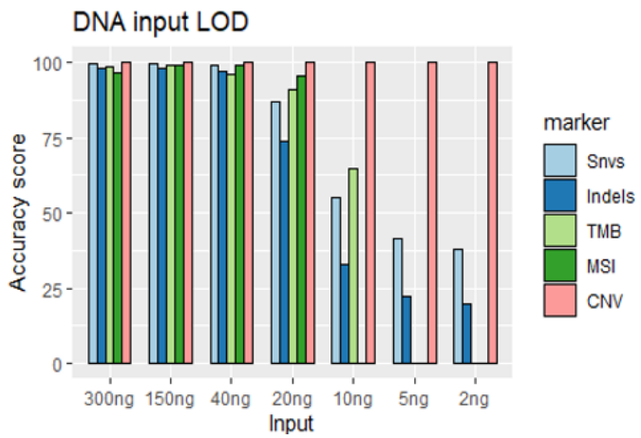
Eurofins Clinical Trial Solutions offers:

- Rapid and accurate genetic analysis of clinical FFPE tissue
- Genomic services to support translational research, and clinical development of precision medicine
- Bioinformatics expertise for analysis, interpretation, and biomarker assay development
- Extensive global testing network
- Improved limits of detection and coverage depth

Custom Bioinformatics Services

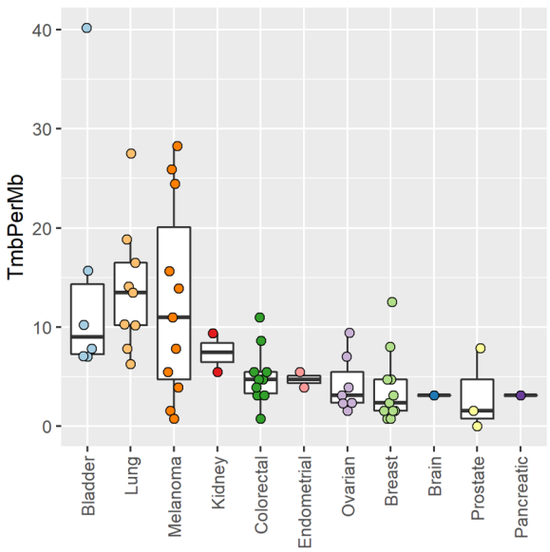
- Clinical interpretation
- Time to event analysis
- Predictive modeling and classification
- Data linkage to clinical endpoints
- Mutational signature analysis
- Pathway analysis
- Open source and proprietary algorithm development

High Sensitivity and Accuracy of DNA Variants

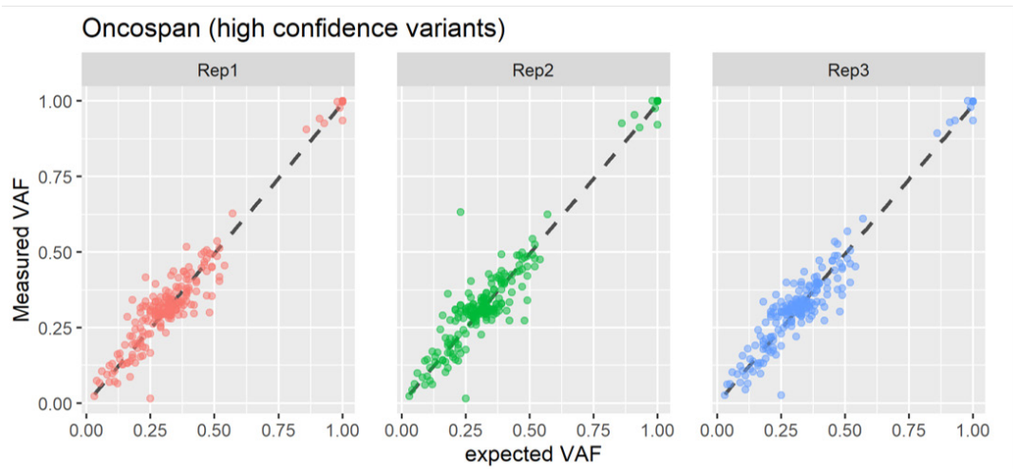


Lower Limit of Detection:
1% VAF at ≥1000X coverage and 40 ng DNA

Analysis of TMB in multiple cancer types:



Reproducible Variable Calling (3 independent operators):



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

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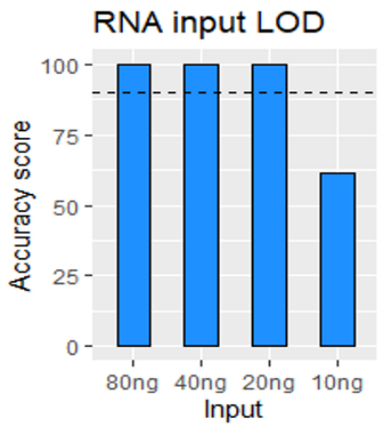
Sensitive and Accurate RNA Fusion Detection:

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	✓	✓	✓	✓

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



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
- **Clinical Interpretation**
- (Knowledge base developed by MD Anderson Cancer Center in partnership with Philips)

Let our experts support your biomarker-driven clinical trial programs with the comprehensive NGS solution that provides proven utility.

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

Eurofins Viracor BioPharma
18000 West 99th Street
Lenexa, KS 66219 USA
clinicaltrials@vbp.eurofinsus.com
Tel +1 800 305 5198
eurofins-viracor.com/biopharma