eurofins | Viracor BioPharma Services

Genomic Profiling for Clinical Development of Precision Medicine

Comprehensive Genomic Sequencing to Identify Somatic Alterations in Tumor Biopsies

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 both FFPE and plasma 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 for both FFPE and ctDNA

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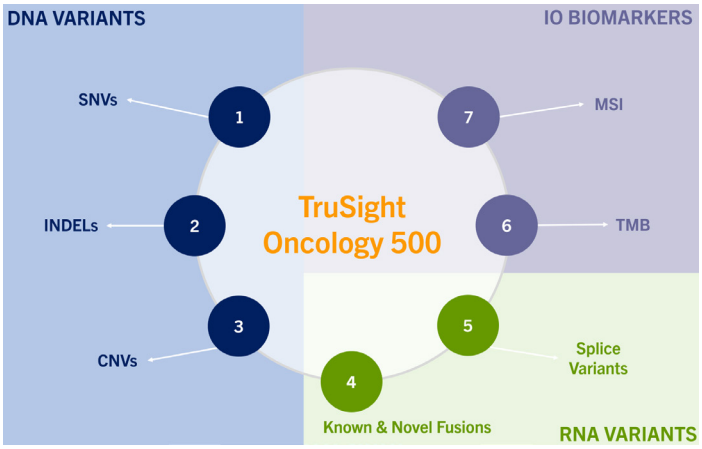
TSO500 is a hybrid capture-based approach targeting 523 oncology-relevant genes, including biomarkers that are both FDA-approved and in the NCCN guidelines.



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 from FFPE and 30ng ctDNA from plasma (for DNA variants only), demonstrating robust analytical performance. In addition to variant calls, the assay reports a tumor mutational burden (TMB) score and microsatellite instability (MSI) status.

PanCancer IQ™ Assay Specifications

Description and Sample Requirements:
FFPE (DNA and RNA); Plasma (DNA only)
Full coding sequence of 523 genes
Variants called:
SNVs
InDels
CNVs
Fusions
Splice Variants (FFPE only)
IO signatures (TMB, MSI)
Panel size:
1.94 Mb DNA; 358 kb RNA (FFPE only)
Sample input:
As little as 40 ng DNA/20ng RNA from FFPE
As little as 30ng ctDNA from plasma
FFPE Sections:
5 um, min 20% cellularity, <20% necrosis
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.

PanCancer IQ™ Performance

CAP/CLIA validated for use with FFPE and Plasma	
Sensitivity:	
VAF limit of detection (LOD):	As low as 15% 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 for FFPE (NPA ≥ 99%):	
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%
Analytical Specificity for Plasma(NPA ≥ 99%):	
Accuracy:	Small variants = 99.5% (98.3% - 99.9% CI)
	SNVs = 100% (78.3% - 100% CI)
	Indels = 97.4% (78.3% - 100% CI)
	CNVs = 100% (78.3% - 100% CI)
	Fusions = 100% (87.1% - 100% CI)
Precision:	Intra-Assay:
	Small variants = 96.7% (89.9% - 99.3% CI)
	Inter-Assay:
	CNVs = 100% (86.5% - 100% CI)
	Fusions = 92.3% (69.3% - 99.2% CI)

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

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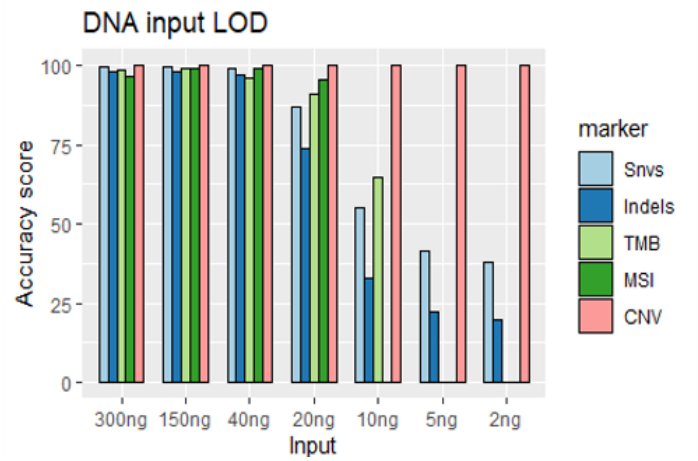
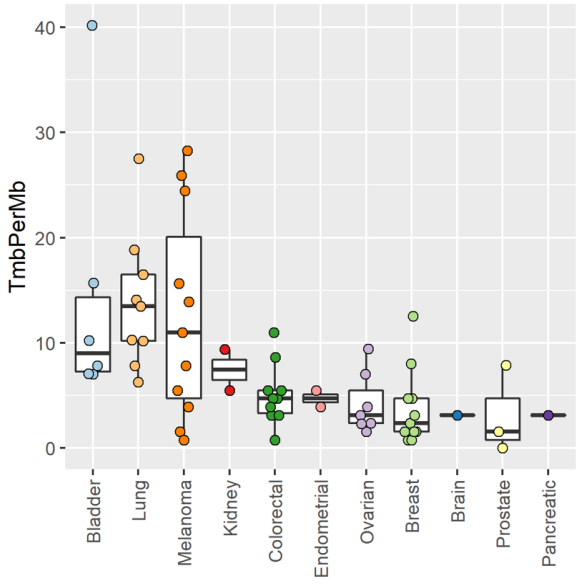
High Sensitivity and Accuracy of DNA Variants

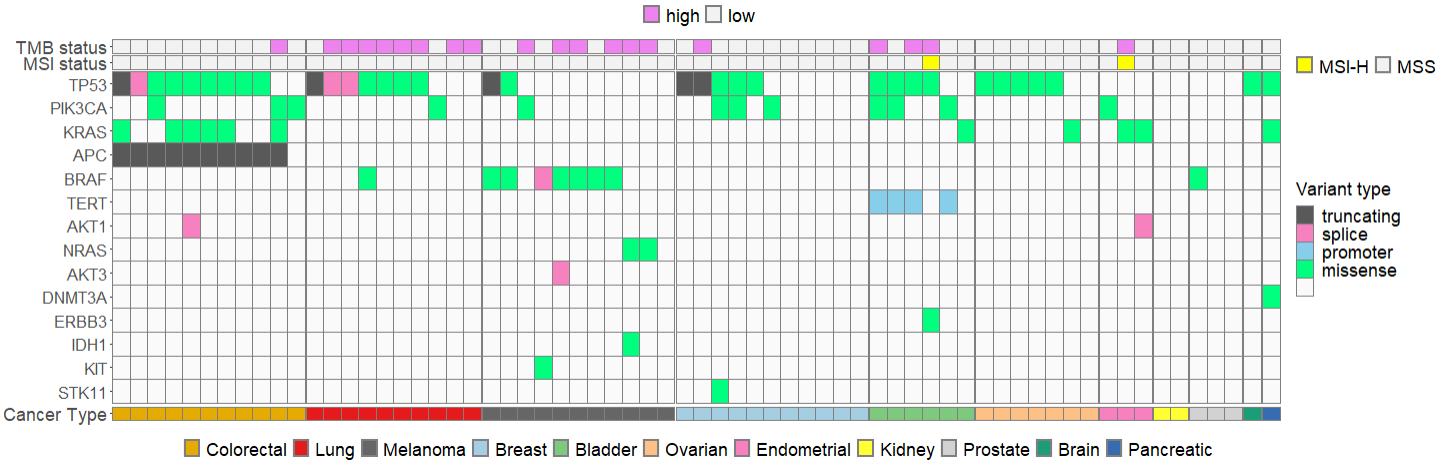


DNA Limit of Detection: 40 ng for SNVs & indels, 20 ng for CNVs, TMB & MSI

TMB analysis in FFPE from multiple indications:



PanCancerIQ Clinical Data Overview:



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

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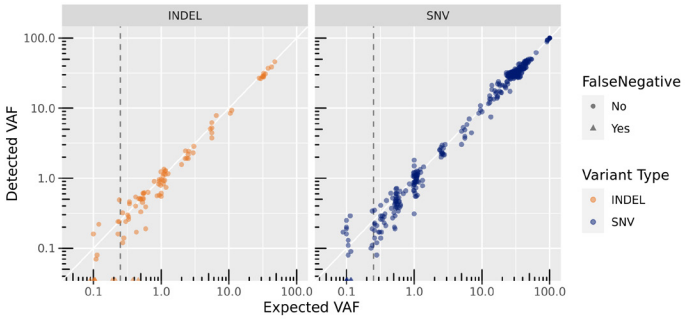
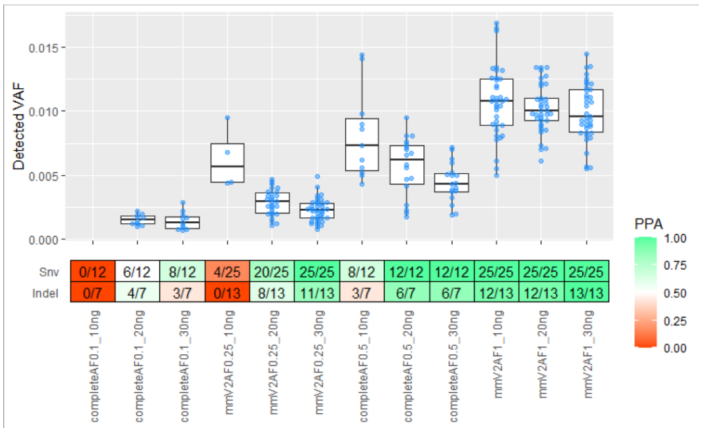
Variant Allele Frequency: Accuracy



Analytical validity – LOD for DNA input



Standard PanCancer IQ™ Data Deliverables

- Standard 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

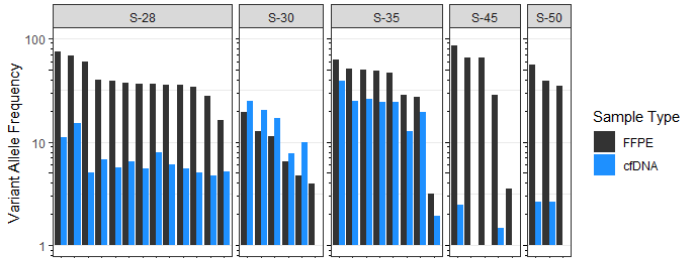
PanCancer IQ™ Clinical Interpretation

Philips IntelliSpace interface powered by MD Anderson Cancer Center knowledgebase PODS, and CureMatch Bionov software

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

Variant Allele Frequency Concordance of Matched FFPE and Plasma Samples



Variant Allele Frequency: AccuracyConcordance of mutations by the PanCancerIQ assay called in matched FFPE and plasma samples in 5 patients across 4 indications.

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.

For more information please scan:

F.P.O

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

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