DISCOVERY LIFE SCIENCES™

Science at your Service™

TECHNICAL DATA SHEET

TruSight™ Oncology 500 (TSO500) Solid Tumor NGS Services

Actionable, comprehensive and sensitive genomic insights to accelerate oncology biomarker programs

Service Overview

Discovery Life Sciences' sequencing and bioinformatics laboratory, HudsonAlpha Discovery, accelerates oncology programs by identifying and validating cancer biomarkers in resected tumor tissues using optimized, high coverage next generation sequencing (NGS) services. Our research-use only (RUO) service leverages highly sensitive Illumina TSO500 sequencing assays and includes comprehensive bioinformatics analysis to simplify decision-making. The TSO500 Solid Tumor assay assesses 523 genes for single nucleotide variants (SNVs), insertions/deletions (InDels), copy number variants (CNVs), Tumor Mutation Burden (TMB), and Microsatellite Instability (MSI) as well as 55 RNA gene fusions to provide pan-cancer genomic biomarker evaluation.

Discovery also offers TSO500 ctDNA analysis of plasma specimens and matched biospecimen sets to advance liquid biopsy applications.

Visit dls.com/TSO500liquidbiopsy to learn more.

Services Highlights

- Accelerate reliable analysis of solid tumor tissues using Discovery's biospecimen procurement, optimized dual DNA/RNA extractions and robust sequencing workflows
- Obtain highly sensitive genomic data at 2% variant allele fractions (AFs) or lower starting with as little as 80 ng of genomic DNA (gDNA) from FFPE or other resected tissues
- Determine TMB and MSI biomarker signatures that facilitate evaluation of potential immunotherapy response
- Streamline interpretation of clinically relevant genomic variants with an annotated TSO500 PDF report from PierianDx

ACCURACY: >99%

LIMIT OF DETECTION: >2% ALLELE FRACTIONS

REPRODUCIBILITY: >97%

Performance Data: *Using commercially available reference standards in our optimized and automated nucleic acid extraction, library construction, and sequencing workflows, we demonstrate the accuracy, sensitivity, and reproducibility of our TSO500 Solid Tumor NGS RUO service.*

Accuracy

When evaluated with the Horizon Discovery OncoSpan gDNA reference standard, our TSO500 Solid Tumor assay detected expected variants across 23 of 23 expected variants at >=2% VAF across all replicates (Table 1).

Using the SeraCare Seraseq® FFPE NTRK Fusion RNA reference standard, we verified that our assay identified fusions with 100% accuracy, detecting 14 out of 14 fusions across multiple replicates (Table 2).

Limit of Detection

Using the TSO500 Solid Tumor (Table 1) assay, we demonstrate highly sensitive detection of SNVs and InDels at the expected AFs, as low as 2%.

Reproducibility

The robust reproducibility of the TSO500 Solid Tumor assay is demonstrated via both intra and inter-run replicates, with R^2 values of 0.97.

Table 1. TSO500 Variant AF Detection in Horizon OncoSpan gDNA HD827 Reference Standard Sample.

Gene	Variant	Horizon OncoSpan gDNA HD827*	Run 1†	Run 2†
APC	p.T1493T	35%	35%	36%
BRAF	p.V600E	11%	8%	9%
BRCA2	p.K1691fs*15	33%	32%	34%
CTNNB1	p.S33Y	33%	36%	28%
CTNNB1	p.S45del	10%	9%	12%
EGFR	p.G719S	25%	24%	22%
EGFR	p.L858R	3%	2%	2%
EGFR	p.E746_A750 delELREA	2%	2%	2%
EGFR	p.Q787Q	15%	16%	14%
FBXW7	p.S668fs*39	33%	28%	31%
FLT3	p.P986fs*>8	10%	11%	10%
KIT	p.D816V	10%	4%	11%
KIT	p.L862L	8%	5%	6%
KRAS	p.G13D	15%	16%	14%
KRAS	p.G12D	6%	6%	6%
MET	p.A1357A	7%	6%	5%
MET	p.L238fs*25	7%	7%	7%
NOTCH1	p.P668S	30%	34%	31%
NRAS	p.Q61K	13%	13%	11%
PIK3CA	p.E545K	9%	8%	9%
PIK3CA	p.H1047R	18%	18%	21%
RET	p.L769L	60%	66%	64%
TP53	p.P72R	93%	93%	92%

* Expected Allelic Frequency % † Averaged Observed Allelic Frequency %

Table 2. TSO500 Fusion Detection in SeraCare Seraseq® FFPE NTRK Fusion RNA Reference Standard Samples.

Gene Pair	Breakpoint 1	Breakpoint 2	Intra-run Fusion Identification	Inter-run Fusion Identification
AFAP1-NTRK2	chr4:7780487	chr9:87356807	✔	✔
BTBD1-NTRK3	chr15:83710478	chr15:88576274	✔	✔
ETV6-NTRK3	chr12:12006493	chr15:88483984	✔	✔
ETV6-NTRK3	chr12:12006493	chr15:88576274	✔	✔
ETV6-NTRK3	chr12:12022900	chr15:88483984	✔	✔
IRF2BP2-NTRK1	chr1:234744193	chr1:156844360	✔	✔
LMNA-NTRK1	chr1:156108394	chr1:156844694	✔	✔
NACC2-NTRK2	chr9:138905045	chr9:87359888	✔	✔
PAN3-NTRK2	chr13:28713224	chr9:87549077	✔	✔
QKI-NTRK2	chr6:163984749	chr9:87482156	✔	✔
SQSTM1-NTRK1	chr5:179252225	chr1:156844362	✔	✔
TFG-NTRK1	chr3:100451513	chr1:156844360	✔	✔
TPM3-NTRK1	chr1:154142876	chr1:156844361	✔	✔
TRIM24-NTRK2	chr7:138258384	chr9:87475952	✔	✔

Conclusions

We have optimized the TSO500 Solid Tumor assay and now offer it as high-quality, robust service on a RUO fee-for-service basis with delivery of FASTQ, BAM, VCF and other files as well as optional PierianDx annotated reports.

Get Started

Learn more about how Discovery Life Sciences can advance your oncology biomarker discovery and development programs by contacting us at **info@dls.com or calling (866) 838-2798.**

HUDSONALPHA DISCOVERY

SEQUENCING + BIOINFORMATICS™

A WORLD-CLASS GENOMIC SERVICES LAB WITH INDUSTRIAL-SCALE CAPABILITIES

HudsonAlpha Discovery brings together advanced technologies, workflows optimized for quality and reproducibility, and an innovative, service-oriented scientific team that delivers reliable scientific insight rapidly and at scale.