

TruSight Oncology 500 (TSO500) Assay

The TruSight Oncology 500 (TSO500) for tissue assay employs a hybrid-capture approach for target enrichment of 523 genes and leverages unique molecular indices to enable detection of low allele frequency SNVs, insertions-deletions (indels), and CNVs. This comprehensive cancer panel interrogates relevant cancer biomarkers with as little as 44 ng of DNA and 40 ng of RNA isolated from FFPE tissue. Beyond these variant types, TSO500 determines tumor mutational burden (TMB) and microsatellite instability (MSI) scores. IQVIA Laboratories can meet your profiling needs by leveraging trusted technology from Illumina® and our expert support team in combination with Genomic Centers in the US, China, Edinburgh, and Singapore.

HIGHLIGHTS

- 44 ng DNA and/or 40 ng RNA input
- TMB and MSI scores
- SNVs, indels, CNVs, fusions, and splice variants
- Full exon coverage for 522 of 523 genes

TMB methodology

The pipeline uses an enhanced algorithm to robustly assess TMB from SNVs and indels detected in the coding regions. TMB is calculated as the number of eligible somatic mutations per Mb. Reports include TMB scores calculated from synonymous and non-synonymous variants that meet the following criteria:

- High-confidence coding regions with $\geq 50\times$ coverage
- Small variants: SNVs and indels (MNVs excluded)
- Variants with observed VAF $\geq 5\%$
- Germline variants filtered based on germline variant databases and VAF

TSO500 panel content

FEATURE	TSO500 PANEL
Panel size	1.94 Mb (DNA), 358 kb (RNA)
Small variants	523 genes
CNV	59 genes
RNA fusions	55 genes
RNA splice variants	3 genes
MSI	130 sites

TSO500 assay specifications

Sample types	Formalin-fixed paraffin-embedded (FFPE) tissue
Sample recommendations	Cumulative tissue area of at least 2 mm ³ , not exceeding 6 mm ³ ; minimum 20% tumor cell content, recommend ≥ 30%
Input requirements	44 ng DNA and/or 40 ng RNA
Sequencing platform	NovaSeq 6000 or NextSeq 500/550
Read depth	≥ 40 M DNA Clusters (≥ 80 M DNA Reads); ≥ 8 M RNA Clusters (≥ 16 M RNA Reads)
Deliverables	FASTQ, BAM, QC report, VCFs, Combined Biomarker Report in text format (Sample QC, Small Variants and Annotations, TMB and MSI scores, CNVs, Fusions, and Splice Variants)
Regulatory	Validated up to CAP/CLIA standards. IQVIA Laboratories offers this TSO500 assay at multiple regulatory levels, from Research Use Only (RUO) to Good Clinical Practices (GCP) to CAP/CLIA, depending on the intended use of the assay by our client. Please reach out to our IQVIA Laboratories Genomics Business Development team to discuss your intended use so we can better guide which regulatory level is most appropriate for your clinical or research program(s)

IQVIA Laboratories global testing footprint



Global consistency
Harmonized assay testing on **3 continents** for consistent results.

Personalized service
Custom turnaround times for **delivery and analysis**.

Massive data delivery
1.2+ petabytes of genomic data globally in 2024.

Decades of Expertise
Over 20 years in genomics testing.

Industry leader
Leading in genomic testing **since 2001**.

Extensive experience working with the **top 10 pharmaceutical companies**.

IQVIA Genomics has partnered with **> 125 leading/top biotech companies**.



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