

Neo Comprehensive – Solid Tumor (TSO500 HT)

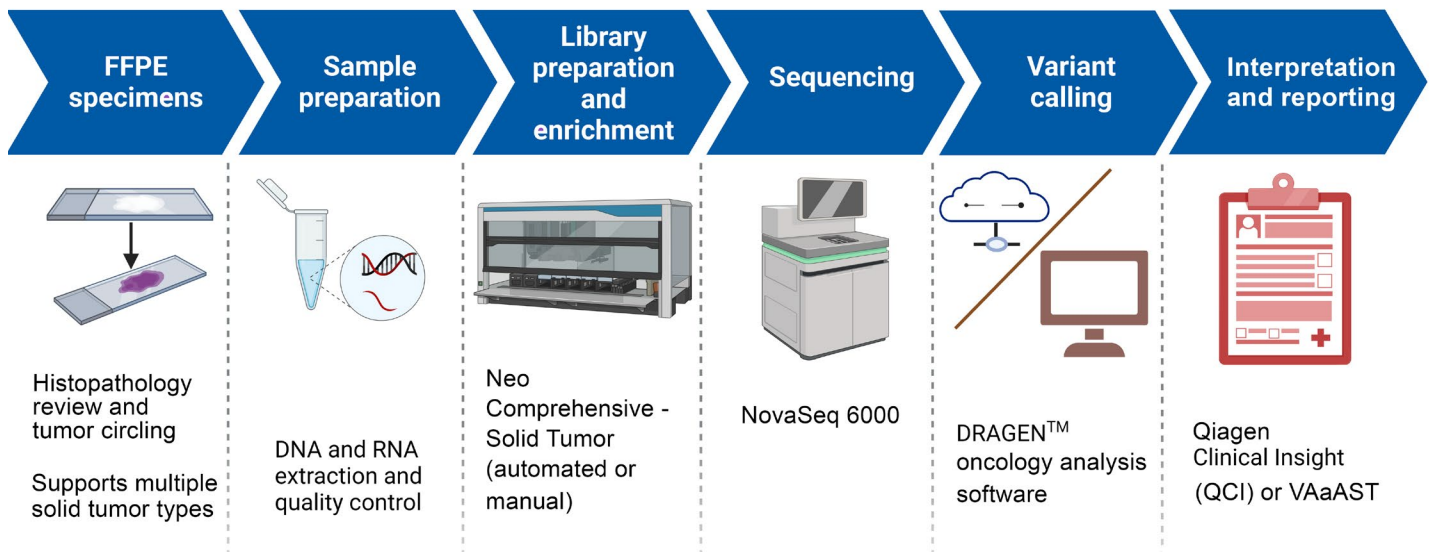


NeoGenomics offers the Neo Comprehensive – Solid Tumor (TSO500 HT) assay to enable comprehensive genomic profiling (CGP) from FFPE samples for multiple cancer types. Neo Comprehensive – Solid Tumor provides comprehensive coverage of cancer-relevant biomarkers across DNA and RNA in a single assay. The NGS panel of 517 genes profiles genetic alterations such as single nucleotide variants (SNVs), insertions/deletions (InDels), copy number variations (CNVs), known/novel fusions, splice variants, and assesses immunotherapy biomarkers such as microsatellite instability (MSI) and tumor mutational burden (TMB)! NeoGenomics provides Neo Comprehensive – Solid Tumor services with a robust, high-throughput workflow and a true end-to-end solution from tissue sample to variant and clinical reporting.

Neo Comprehensive – Solid Tumor Services

- End-to-end CGP solution from sample accessioning, histopathology, and laboratory work-up to data analysis and reports
- Consolidating complex, separate diagnostic tests while conserving tissue, saving time and costs
- Comprehensive coverage of established and emerging biomarkers for multiple cancer indications
- Analytically validated to the highest standards in our CAP/CLIA laboratory
- Ready to deploy for research studies and clinical trials
- Clinical reporting and/or CDx development available

Figure 1. End-to-end comprehensive genomic profiling solution from sample to report



Integrated workflow and one-stop solution

NeoGenomics offers services as an integrated, one-stop comprehensive genomic profiling solution (Figure 1, Table 1). With Hamilton liquid-handling, NovaSeq 6000, and DRAGEN™ variant calling pipeline, lab and data analysis workflows can be highly automated, enabling consistent results, quick TATs and high throughput (Table 1). Additionally, the use of unique molecular identifiers (UMIs) and hybrid-capture chemistry in Neo Comprehensive – Solid Tumor enables variant detection at low allele frequencies as well as provides high analytical specificity. NeoGenomics can also provide clinical reporting for clinical trial projects and/or leverage our deep expertise for CDx development.

Table 1. Neo Comprehensive – Solid Tumor assay specifications

Parameter	Neo Comprehensive – Solid Tumor
Sample types	FFPE tissue
Sample recommendation	> 20% tumor content
Chemistry	Hybrid-capture
Sequencing system	NovaSeq 6000
Panel size	1.94 Mb DNA, 358 kb RNA
Min. nucleic acid input	60 ng DNA, 80 ng RNA
Sample throughput	48 sample (or higher) per run
Deliverables	FASTQs, BAMs, QC report, VCFs, Fusions, MSI and TMB scores, and clinical report
Target TAT	~ 10 days real-time testing 2-3 weeks for batched testing

Robust and sensitive assay

We have implemented strict quality controls and monitor key quality metrics throughout the sample accessioning, histopathology, nucleic acid extraction, library preparation, Neo Comprehensive – Solid Tumor assay and variant calling analysis. These measures ensure a robust and reproducible process, resulting in the highest quality data and results. Neo Comprehensive – Solid Tumor has been validated in our CAP/CLIA San Diego, California, high throughput genomics lab. The assay is

References: 1. TSO500 and Neo Comprehensive – Solid Tumor datasheet
2. Analytical validation of Neo Comprehensive – Solid Tumor (TSO500 HT)

validated to the highest standards with multiple orthogonal and/or confirmatory assays.² Neo Comprehensive – Solid Tumor demonstrates excellent performance in detecting SNVs, indels, CNVs, gene fusions and splice variants, and in MSI and TMB assessment. Furthermore, the results show high concordance with NeoTYPE® Discovery Solid Tumor and other NeoGenomics molecular assays that our Clinical Division has been employing for clinical diagnostic testing. Table 2 summarizes the performance parameters of the Neo Comprehensive – Solid Tumor assay. Figure 2 shows a high concordance of TMB detection with NeoGenomics' in-house assays across multiple cancer types. For details on the validation study design and results, please see our Neo Comprehensive – Solid Tumor assay Validation White Paper (available upon request).

Table 2. Neo Comprehensive – Solid Tumor assay performance

Parameter	Performance
SNVs	95% Sensitivity, > 99% Specificity
InDels	94% Sensitivity, > 99% Specificity
Fusions	91% Sensitivity, > 99% Specificity
CNV	100% Sensitivity, > 99% Specificity
MSI	Concordance 94%
TMB	Concordance 93%

Figure 2. High Concordance of TMB readout

