NEO | PanTracer™ LBx

NEO | PanTracer LBx is NeoGenomics' comprehensive liquid biopsy test for pan-solid tumor. PanTracer LBx leverages Illumina's updated TSO500 ctDNA v2 chemistry for cancer research and discovery applications, providing biomarker results from cfDNA, even when sufficient tissue samples may not be available.

Comprehensive Genomic Profiling:

517 gene panel covering all major variant classes including IO gene signatures

- SNVs
- InDels
- Fusions
- CNVs
- MSI & bTMB scores

Flexible Sample Input:

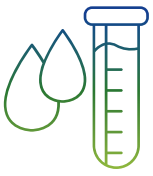
Results from as little as **10ng cfDNA** input.
Our laboratory is able to process:

- Whole blood
- Frozen plasma
- Extracted cfDNA derived from plasma

High Performance Assay:

- PanTracer LBx enables detection of variants down to **0.2% VAF with a >99.9% specificity**

Comprehensive panel of 517 genes



Results from liquid biopsy samples

Sensitive yet specific variant detection

Assay specifications:

PanTracer LBx is a comprehensive genomic profiling NGS assay designed to detect key classes of genomic variants, SNVs, InDels, CNVs and Fusions, as well as gene signatures from liquid biopsy samples including MSI and bTMB. PanTracer LBx leverages the TSO500 ctDNA v2 chemistry and Illumina's DRAGEN variant calling pipelines.

NeoGenomics handles the entire end-to-end wet lab workflow from cfDNA extraction to report output and provides project management support throughout the duration of the project. NeoGenomics offers flexible data outputs including annotated files, QC, and raw sequencing files.

Assay validation:

PanTracer LBx has been analytically validated as a RUO assay. Validation studies included LOD, LOB, sensitivity, specificity, and precision studies as well as orthogonal testing with clinical samples.

LOD was assessed utilizing SeraSeq® Complete ctDNA reference material at both 10ng and 20ng input levels across multiple VAF intervals. Analytical sensitivity was assessed across a range of 1 – 5x LOD for all four variant classes. Analytical specificity was calculated per-base from sequencing 22 healthy donor samples; from the same experiment, the false positive rate per base was determined.

Additionally, orthogonal testing with clinical samples was performed comparing an amplicon-based sequencing platform to PanTracer LBx. 101 variants from 9 clinical samples were assessed. Samples were obtained from Stage III and IV patients with various advanced solid tumors including lung, colorectal, melanoma, as well as other malignancies. PanTracer LBx called 99/101 variants concordantly with no false positive results.

LBx = liquid biopsy, cfDNA = cell free DNA, NGS = next generation sequencing, RUO= research use only, SNV = single nucleotide variant, InDel = insertion deletion, CNV = copy number variation, MSI = Microsatellite instability, bTMB = blood tumor mutational burden, VAF = variant allele frequency

References: 1- Illumina TruSight™ Oncology 500 ctDNA v2 Data Sheet M-GL-02196 v2.0, 2 – NEO | PanTracer LBx Validation Report, internal data on file

*Hyperlink to Gene List

Table 1: PanTracer LBx Assay Specifications

Parameter	Specification
Chemistry	Hybrid capture
Sequencer	NovaSeq 6000 (RUO)
Batch size	22 samples
Turnaround Time	14-16 days, batched
Panel size	1.94 Mb
Panel content*	SNVs and InDels – 517 genes CNVs – 59 genes Fusions – 23 genes MSI score – over 2,300 loci bTMB score – over 1Mb
Sample types	Whole blood Plasma cfDNA from plasma
cfDNA input	10ng minimum; 20ng preferred
Sequencing read run length	2 x 151bp
Sequencing coverage	35,000x raw coverage
Laboratory	Cambridge, UK (CAP accredited)
Validation level	RUO
Data Deliverables	Annotated VAaAST files, FASTQs, BAMs, VCFs, QC report

Table 2: Validation Performance Data

Parameter	Performance
Limit of detection (LOD)	0.2% VAF for SNVs 0.5% VAF for InDels 0.5% VAF for Fusions 1.23-fold change for CNVs
Analytical Sensitivity	99.14% for SNVs 96.36% for InDels 94.11% for Fusions 100% for CNVs
Analytical Specificity	99.9996%
Limit of blank (LOB)	0.0007% per base
Precision	Intra-run = 95.2% Inter-run = 95.0%
Concordance	98.02%

NEO GENOMICS

9490 NeoGenomics Way
Fort Myers, FL 33912
Phn: 866.776.5907
Fax: 239.690.4237

neogenomics.com

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