BIOPHARMA SOLUTIONS

OmniSeq® INSIGHT: Comprehensive genomic and immune profiling for solid tumors

Advance your biomarker-driven and immunotherapy development programs with comprehensive tissue, liquid biopsy and tumor-immune profiling solutions.

Treatment strategies tailored to individual patients based on their immune profile and tumor characteristics can provide more effective and durable anti-cancer responses. Understanding the genomic and immune changes in a tumor and tumor microenvironment is essential for identifying mechanisms and biomarkers that can drive the development of new precision therapeutics.

Labcorp's OmniSeq INSIGHT portfolio can help you accelerate therapeutic development by providing valuable insights into cancer-related pathways. Our gene expression and genomic profiling assays deliver clear, comprehensive views of biomarker status to support you from biomarker discovery, biomarker validation and exploratory endpoint analysis to optimizing patient selection and stratification for clinical trials.

Product portfolio

OmniSeq INSIGHT
Comprehensive solid tumor analysis
Available as combined or stand-alone services:

- **Genomic Profiling**
  523 genes | MSI | TMB
- **Immune Profiling**
  RNA expression 395 genes | HLA

OmniSeq INSIGHT ctDNA
Liquid-biopsy based solid tumor profiling
523 genes | bMSI | bTMB

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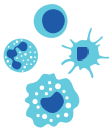
OmniSeq INSIGHT Genomic Profiling Assay

Comprehensive coverage of genomic alterations across solid tumor types

- A comprehensive panel comprising clinical practice guideline-recommended biomarkers provides rich variant information
- Reports all four main classes of genomic alterations, fusions and splice variants plus microsatellite instability (MSI) and tumor mutational burden (TMB) genomic signatures leveraging the robust DRAGEN pipeline
- Can be run as a stand-alone assay or in combination with the OmniSeq INSIGHT Immune Profiling Assay

OmniSeq INSIGHT Immune Profiling Assay

Targeted NGS assay for comprehensive immune profiling



- Expression profiling of 395 immune-related genes to decipher heterogeneity of the tumor microenvironment and identify potential biomarkers for immunotherapy
- Simultaneously analyze immune markers and signaling pathways for assessment of immune response, immune cell function and identification of molecular signatures and immune cell subsets predictive of therapeutic outcomes
- Bioinformatic reporting includes proprietary gene expression signatures that provide novel mechanistic insights
- Can be run as a stand-alone assay or in combination with the OmniSeq INSIGHT Genomic Profiling Assay

OmniSeq INSIGHT ctDNA

Pan solid-tumor liquid biopsy CGP for cancer research

- Complements OmniSeq INSIGHT genomic profiling, providing valuable information even when tumor sample is limited or unavailable
- A fast, reliable option for liquid biopsy assessment leveraging powerful TSO500 v2 chemistry, a 98% sequencing QC pass rate and DRAGEN servers for rapid, ultra-sensitive analysis

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Assay	OmniSeq INSIGHT		OmniSeq INSIGHT ctDNA
	Genomic profiling	Immune profiling	
Intended use	**LDT or RUO**	**LDT or RUO**	**RUO**

Targets	• Full coding sequence of 523 cancer-related genes
	  • SNVs, indels, amplifications, translocations
	  • MSI and TMB biomarkers
	• RNA sequencing of 55 genes
	  • Fusions and splice variants
		• Expression profiling of 395 immune-related genes (64 clinically validated)
		  • PD-L1, HLA Class I genotypes, cancer testis antigens
		  • T-cell priming/trafficking, T-cell recognition, T-cell infiltration, cytotoxic T-cells
			• Full coding sequence of 523 cancer-related genes
			  • SNVs, indels, amplifications, translocations
			  • bMSI and bTMB biomarkers

Analysis	DNA and RNA from FFPE tissue	RNA from FFPE tissue	ctDNA derived from plasma
Sample input	10 mg tissue or 10 x 5 µm unstained slides or 40-100 ng DNA and 20-80 ng RNA	3-5 x 5 µm unstained slides or RNA as low as 10 ng; 20-80 ng recommended	As low as 10 ng; 20 ng cfDNA recommended
	Combined assay with PD-L1 testing: 10 mg tissue or 20x5 µM unstained slides or 40-100 ng DNA and 30-100 ng RNA		N/A
Sequencing coverage	750x	2M reads	>1300x with UMIs
Turnaround time	Prospective testing: as few as 7-10 days; Exploratory/retrospective testing: SOW dependent	Prospective testing: as few as 7-10 days; Exploratory/retrospective testing: SOW dependent	As few as 7-10 days
Data outputs (Format)	Sequences (FASTQ); alignments (BAM); SNV, indel and CNV variant calls (VCF); MSI, TMB and run QC metrics (JSON); combined variant and run metrics file (TSV)	Sequences (FASTQ); alignments (BAM); sample QC, absolute reads, background subtracted read count, RPKM, gene expression rank (CSV); custom bioinformatics signatures	Sequences (FASTQ); alignments (BAM); SNV, indel and CNV variant calls (VCF); bMSI, bTMB and run QC metrics (JSON); combined variant and run metrics file (TSV)

Robust solutions for biomarker-driven therapeutic development

Comprehensive
Broad panels maximize relevant insights from cancer-related variants and immune gene expression

Accurate
Optimized workflows provide high coverage—even with low quality samples—to measure gene and transcript abundance as well as identify known and new features

Reliable
Highly optimized and robust validation to ensure optimal coverage in low quality samples

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WHY LABCORP

One partner to achieve your next cancer breakthrough

At Labcorp, we provide industry-leading biopharma services and solutions to help you discover, develop and deliver life-changing therapies that increase the potential to save the lives of people around the world. Built on a reputation for scientific and technical excellence and an unmatched global network, we can support you at every stage of the cancer research continuum.

Deep scientific knowledge and experience:
Access comprehensive and specialized oncology expertise with our integrated medical, scientific, regulatory and statistical teams

Development acceleration:
Reduce development time and risk with end-to-end support from discovery through diagnostic commercialization

Data-driven insights:
Optimize biomarker-driven development with unparalleled data and real-world evidence

Global laboratory network:
Ensure day-one readiness with global drug and diagnostic co-development and test commercialization capabilities

- Partnered with biopharma on 100% of oncology drugs approved by the FDA in 2022
- Experience supporting clinical trial testing for 2,000+ trials across various tumor types
- Supported CDx development for PD-L1, HER-2, KRAS, EGFR, BRAF, ALK and more

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Contact us

Contact our biopharma team to see how we can help you accelerate your precision oncology program.

Learn more at oncology.labcorp.com/biopharma-partners

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