BIOPHARMA

Solid tissue profiling solutions

Reduce development time and costs while maximizing patient stratification and accelerating biomarker selection with solid tumor profiling solutions from Labcorp Oncology.

Current landscape for solid tissue NGS profiling

The drug discovery landscape is shifting. Research and development are growing in cost and complexity. New treatment strategies, including biomarker-driven therapies and cancer immunotherapies, are proving more effective. To bring the power of precision medicine to more patients, pharmaceutical companies need to compress timelines, lower costs and reduce failure rates. From biomarker discovery to CDx commercialization, Labcorp Oncology's solid tissue profiling solutions can help streamline, scale and strengthen your drug development pipeline.

OmniSeq INSIGHT® | LDT

One comprehensive assay for genomic and immune profiling of solid tumors

Improve biomarker discovery, accelerate timelines and maximize patient stratification with OmniSeq INSIGHT®, a comprehensive tissue-based genomic and immune profiling test that uses next generation sequencing to enhance precision cancer drug development.

- **Targets covered:** 523 for genomic profiling, 395 for immune profiling and PD-L1
- **Analysis:** DNA, RNA and proteins
- **Specimen type:** FFPE tissue
- **Sample input:** 10 mg tissue or 20x5 µm unstained slides or 40-100 ng DNA and 30-100 ng RNA from FFPE tumor tissue
- **Sequencing coverage:** 750x
- **Turnaround time:** 10-14 days
- **Assesses:** DNA full exonic coding, RNA fusions, mRNA expression, PD-L1 by IHC, HLA Class I genotypes, MSI, TMB, TCRs, TILs, NK, Cancer Testis Antigens
- **Gene list:** View full list here
- **OmniSeq corporate & lab certifications:** ISO 13485:2016, CAP/CLIA, NY State CLEP

Comprehensive

Evaluate 523 genes across all variant types, including SNVs, indels, CNAs, fusions/splice variants including genes associated with homologous recombination repair deficiency (HRR/HRD), MSI, TMB, expression of 64 clinically validated immune genes, and PD-L1 by immunohistochemistry.

Accurate

With DNA and RNA sequencing, you can accurately measure gene and transcript abundance, identify known and novel features and ensure optimal coverage in low-quality samples.

Flexible

Offering the ability to decouple the assay to best support the needs of your specific program.

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PGDx elio® TISSUE COMPLETE | IVD

The first and only FDA-cleared tumor profiling kitted solution

Accelerate your biomarker-driven clinical trial and CDx development with PGDx elio® tissue complete, an FDA-cleared, CE-IVD marked sample-to-answer solution that includes fully automated bioinformatics and dedicated customer support.

- **Genes covered:** 505
- **Specimen type:** FFPE tissue
- **Sample input:** 50 ng minimum (100 ng recommend)
- **Sample pass rate:** 92.9%
- **Turnaround time:** 5 days*
- **Gene list:** View full list **here**
- **PGDx corporate & lab certifications:** ISO 13485:2016, ISO 15189:2012, CAP/CLIA, NY State CLEP

*From nucleic acid extraction to analytical report. Turnaround time for kitted workflow only.

Rapid

Receive actionable results in as little as 5 days* with only 6 hours of hands-on time.
*From nucleic acid extraction to variant report. Turnaround time for kitted workflow only.

Reliable

Identify somatic mutations, including SNVs, indels, MSI, TMB, and select amplifications and translocations, with high sensitivity and specificity (>99%).

Proven Quality

Built under design control to withstand the rigors of the FDA approval process for use in prospective clinical trials and companion diagnostic development.

Global availability as a biopharma service

PGDx elio® tissue complete will be available as a service offering from the Labcorp laboratories in Geneva, Switzerland, and Shanghai, China, in 2024.

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Range of methods to drive fit-for-purpose insights in biomarker discovery

WHOLE TRANSCRIPTOME SEQUENCING | RUO

By analyzing both coding and multiple forms of non-coding RNA, whole transcriptomic analysis provides deeper interrogation of complex changes in biological processes. The comprehensive, unbiased approach allows researchers to identify biomarkers across the broadest range of transcripts. This enables a better understanding of phenotypes of interest and can de-risk drug development by optimizing assay design and improving clinical trial efficacy.

- **Specimen type:** FFPE / PBMC / blood
- **Analysis:** RNA
- **Key types of sequencing:**
  - Global transcript expression
  - Differential RNA expression
  - Neoantigen prediction
  - Total RNASeq + globin and rRNA depletion
  - Stranded total RNASeq
  - Stranded mRNA RNASeq
  - RNA exome capture RNASeq
  - Globin + rRNA depletion followed by stranded mRNA

WHOLE EXOME SEQUENCING | RUO

By focusing on exons, whole exome analysis provides a high-level of variant information with reduced time for sample to result. In addition, because of the targeted approach, data sets are more manageable and costs optimized.

- **Specimen type:** FFPE / PBMC / blood
- **Analysis:** DNA
- **Key coverage:** 22,0000 genes
- **Performance:** Germline 100X, somatic 250X-500X

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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 care 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:** Prepare for day-one readiness with global drug and diagnostic co-development and test commercialization capabilities

- Partnered with biopharma on 10 of 16 of oncology drugs approved by the FDA in 2022
- Supported CDx development for PD-L1, HER-2, KRAS, EGFR, BRAF, ALK and more
- Experience supporting clinical trial testing for 2,000+ trials across various tumor types

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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 **www.oncology.labcorp.com/biopharma-partners**

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