



**ALL SOLID TUMORS**

# OmniSeq INSIGHT<sup>®</sup>

Make confident treatment decisions  
based on the entire tumor profile



# OmniSeq INSIGHT<sup>®</sup>

## Pan-solid tumor profiling

Using NGS technology, OmniSeq INSIGHT evaluates genomic alterations and immune-related biomarkers within a patient's tumor.

The report delivers a comprehensive summary of FDA-approved therapies, immunotherapies and eligible clinical trials for your patient's solid tumor.

From a single tumor biopsy, analyzed by advanced DNA and RNA NGS technology, OmniSeq INSIGHT identifies treatment options in **one comprehensive, easy-to-read report**.



FFPE tissue

- Resection specimens
- Needle core biopsies
- Cell blocks from FNA



- Multiplex DNA and RNA NGS platform
- Protein expression (PD-L1)

### Identify approved drug candidates

#### Comprehensive genomics

- Identifies genomic alterations in 523 genes
- Fusions/splice variants using RNA-Seq hybrid capture
- Coverage of clinical practice guideline--recommended biomarkers across solid tumor types

### Immunotherapy eligibility

#### Comprehensive immune profiling

- PD-L1 immunohistochemistry (IHC)
- MSI & TMB profiling\*
- Immune biomarker drug targets

### Eligible clinical trials

#### List of patient-eligible clinical trials within 200 miles of patient's physical address<sup>1</sup>

- Testing for biomarkers with clinical trial associations

### The result report includes:

- A summary page of marker findings, including pertinent negatives
- Therapy considerations section with treatment setting, approval status and multi-marker associations
- Flags potential cancer-associated hereditary variants

## A consolidated assay for two different treatment paradigms:



### Genomic profiling

- 523 gene NGS panel
- MSI and TMB\*
- DNA and RNA sequencing
- SNVs, indels, CNAs and fusions\*
- Interrogation of full coding regions
- HLA genotyping



### Immune profiling

- PD-L1 immunohistochemistry (IHC)
- 64 RNA expression/immune profiling genes by immune cycle step:
  - T-cell priming/trafficking
  - T-cell recognition
  - T-cell infiltration
  - Killing cancer cells
  - Cancer testis antigens

## Why choose OmniSeq INSIGHT?

INSIGHT is the only comprehensive test to contain all of the following:

- Genes aligned with FDA approvals, professional practice guidelines and clinical trials
- HRR/HRD-related\* genes for PARP therapeutic selection
- Full coding region coverage for each gene which improves variant detection compared to “hotspot” testing strategies
- An RNA-seq hybrid capture approach which allows for the detection of common and novel fusions
- Targeting of unique emerging and actionable markers
- Immune gene expression (mRNA) analysis to evaluate the interaction between the tumor and its microenvironment
- HLA genotyping to identify HLA Class I alleles at HLA-A, HLA-B, and HLA-C genes

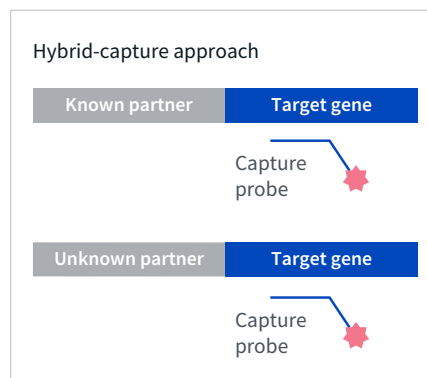
## When to consider OmniSeq INSIGHT:

INSIGHT may be useful as a tool in various clinical settings, including:

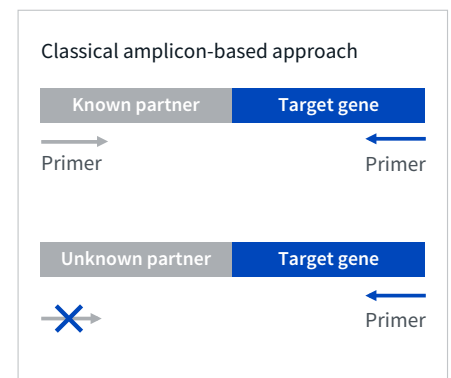
- For patients with advanced and recurrent cancer when evidence-based guidelines recommend broad genomic profiling for evaluation of alterations to guide targeted therapy
- When considering clinical trials as an option for treatment and a patient’s unique genomic and/or immune profile facilitates enrollment
- When a cancer lacks an effective standard-of-care therapy or when a tumor is poorly differentiated and of uncertain origin
- When relapse or disease progression has occurred after prior therapies
- Use of HLA genotype as a biomarker for patient inclusion in immunotherapeutic clinical trials requiring MHC Class I status

## OmniSeq INSIGHT delivers the distinct advantage of leveraging three NGS technologies, leading to the highest quality results:<sup>2</sup>

- DNA sequencing to detect SNVs, indels, CNAs, TMB and MSI
- RNA sequencing by hybrid-capture to detect known and unknown fusion partners
- RNA gene expression profiling provides novel, differentiating insights into the tumor immune microenvironment



Identifies both known and unknown fusion partners



This approach fails to identify unknown fusion partners

\*MSI – microsatellite instability; TMB – tumor mutational burden; SNVs – single nucleotide variants; indels – insertions/deletions; CNAs – copy number alterations; HRR – homologous recombination repair; HRD – homologous recombination deficiency; PARP – poly-ADP ribose polymerase;

## Sample requirements (include pathology report)

Formalin fixed paraffin embedded (FFPE) tissue

- Resection specimens
- Needle core biopsies
- Cell blocks from fine needle aspirates (FNAs)

**\*\*Do not submit decalcified specimens, cytology smears or samples from hematologic malignancies\*\***

FFPE block (preferred) or 20 unbaked, positively charged, unstained slides cut at 5 µm plus one H&E.

## Proven expertise in FFPE sample processing

A proprietary pre-analytical FFPE extraction process maximizes our ability to yield DNA and RNA sequencing data from limited specimens.



### OmniSeq® high laboratory quality standards

- NYS CLEP approved
- ISO 13485 (2016) certified
- CLIA and CAP accredited



### Labcorp broad national coverage

- In-network with most major health plans
- 1,600 contractual relationships with plans, payers and other health care organizations

## Powering better decisions

When you need trusted information to make clear, better health decisions, consider us your source for oncology testing. Whether you are advancing therapies through clinical trials or diagnosing and treating individuals with cancer, we know you are working relentlessly to improve patient outcomes. We can help.

### Results reporting

Turnaround time of 12-14 days

### Extensive managed care contracts

Help patients maximize their benefits.

### Genetic counseling

A national network of genetic counselors to help inform and support your patients. Call us at 855-GC-CALLS or 855-422-2557.

### Call us

Arizona: 800-710-1800  
Connecticut: 800-447-5816  
North Carolina: 800-345-4363  
Tennessee: 800-874-8532

### Schedule a pickup

Toll-free (within the US) at 866-875-2271

### Visit us

[oncology.labcorp.com](https://oncology.labcorp.com)

## References

1. OmniSeq Bioinformatics Knowledgebase - data curation September 2022.
2. Conroy JM, et. al., A scalable high-throughput targeted next-generation sequencing assay for comprehensive genomic profiling of solid tumors. *PLoS One*. 2021 Dec 2;16(12):e0260089.

For more information about OmniSeq INSIGHT visit [oncology.labcorp.com/omniseq](https://oncology.labcorp.com/omniseq), or contact your Labcorp Oncology sales representative.

