9-12 day TAT*

ALL SOLID TUMORS

# OmniSeq® INSIGHT

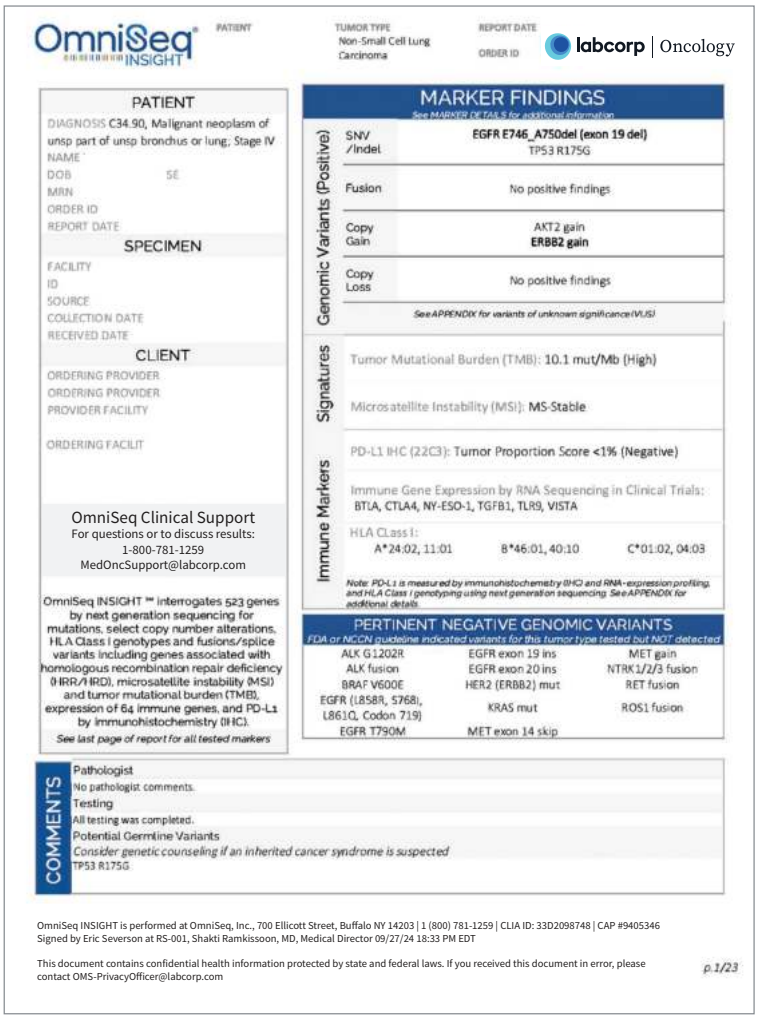
Make confident treatment decisions based on the entire tumor profile

labcorp | Oncology

# OmniSeq® INSIGHT

## Pan-solid tumor profiling

Analyzing a single tumor biopsy with advanced DNA and RNA next-generation sequencing (NGS) technology, OmniSeq INSIGHT can identify treatment options in **one comprehensive, easy-to-read report**.



OmniSeq INSIGHT | PATIENT | TUMOR TYPE: Non-Small Cell Lung Carcinoma | REPORT DATE | ORDER ID | labcorp | Oncology

**PATIENT**
DIAGNOSIS C34.90, Malignant neoplasm of unsp part of unsp bronchus or lung; Stage IV
NAME
DOB SE
MRN
ORDER ID
REPORT DATE

**SPECIMEN**
FACILITY
ID
SOURCE
COLLECTION DATE
RECEIVED DATE

**CLIENT**
ORDERING PROVIDER
ORDERING PROVIDER
PROVIDER FACILITY
ORDERING FACILIT

OmniSeq Clinical Support
For questions or to discuss results:
1-800-781-1259
MedOncSupport@labcorp.com

OmniSeq INSIGHT ™ interrogates 523 genes by next generation sequencing for mutations, select copy number alterations, HLA Class I genotypes and fusions/splice variants including genes associated with homologous recombination repair deficiency (HRR/HRD), microsatellite instability (MSI) and tumor mutational burden (TMB), expression of 64 immune genes, and PD-L1 by immunohistochemistry (IHC).
*See last page of report for all tested markers*

**MARKER FINDINGS**
*See MARKER DETAILS for additional information*

Genomic Variants (Positive)

| | |
|---|---|
| SNV /Indel | **EGFR E746_A750del (exon 19 del)** TP53 R175G |
| Fusion | No positive findings |
| Copy Gain | AKT2 gain **ERBB2 gain** |
| Copy Loss | No positive findings |

*See APPENDIX for variants of unknown significance (VUS)*

Signatures
Tumor Mutational Burden (TMB): **10.1 mut/Mb (High)**
Microsatellite Instability (MSI): **MS-Stable**

Immune Markers
PD-L1 IHC (22C3): **Tumor Proportion Score <1% (Negative)**
Immune Gene Expression by RNA Sequencing in Clinical Trials: BTLA, CTLA4, NY-ESO-1, TGFB1, TLR9, VISTA
HLA Class I: A*24:02, 11:01 | B*46:01, 40:10 | C*01:02, 04:03

*Note: PD-L1 is measured by immunohistochemistry (IHC) and RNA-expression profiling, and HLA Class I genotyping using next generation sequencing. See APPENDIX for additional details.*

**PERTINENT NEGATIVE GENOMIC VARIANTS**
*FDA or NCCN guideline indicated variants for this tumor type tested but NOT detected*

| | | |
|---|---|---|
| ALK G1202R | EGFR exon 19 ins | MET gain |
| ALK fusion | EGFR exon 20 ins | NTRK1/2/3 fusion |
| BRAF V600E | HER2 (ERBB2) mut | RET fusion |
| EGFR (L858R, S768I, L861Q, Codon 719) | KRAS mut | ROS1 fusion |
| EGFR T790M | MET exon 14 skip | |

**COMMENTS**
Pathologist
No pathologist comments.
Testing
All testing was completed.
Potential Germline Variants
*Consider genetic counseling if an inherited cancer syndrome is suspected*
TP53 R175G

OmniSeq INSIGHT is performed at OmniSeq, Inc., 700 Ellicott Street, Buffalo NY 14203 | 1 (800) 781-1259 | CLIA ID: 33D2098748 | CAP #9405346
Signed by Eric Severson at RS-001, Shakti Ramkissoon, MD, Medical Director 09/27/24 18:33 PM EDT

This document contains confidential health information protected by state and federal laws. If you received this document in error, please contact OMS-PrivacyOfficer@labcorp.com

p.1/23

**All components of the OmniSeq INSIGHT test are fully resulted on greater than 93% of completed cases.**

### FFPE** tissue

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

### 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 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[1]

- 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 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?

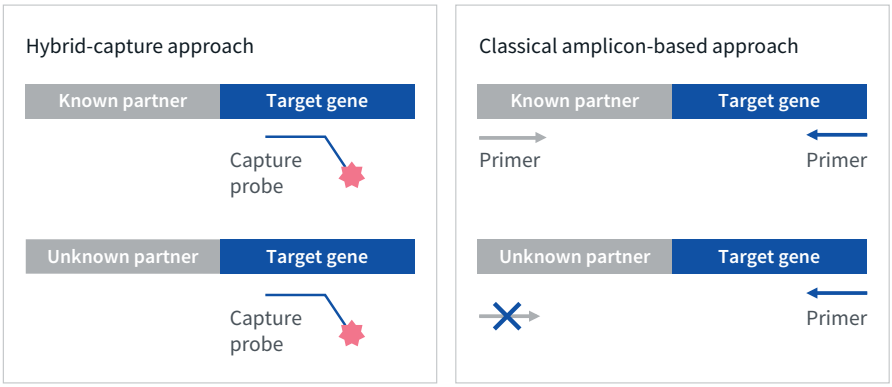
- Genes aligned with FDA approvals, professional practice guidelines and clinical trials
- HRR/HRD-related genes for PARP therapeutic selection**
- Full coding region coverage for each gene, which improves variant detection compared to "hotspot" testing strategies
- An RNA-seq hybrid capture approach that 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:

- 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 requires MHC** Class I status

## OmniSeq INSIGHT delivers the distinct advantage of leveraging three NGS technologies, leading to the highest quality results:[2]

- 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

## 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.

### Labcorp's high laboratory quality standards

- NYS CLEP approved
- ISO 13485:2016 and ISO 15189:2012
- CLIA and CAP accredited

### Labcorp's broad national coverage

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

### Result reporting

Turnaround time of 9-12 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


**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.


*Turnaround time is reported based on the number of days from sample receipt in the lab to release of clinical report

**FFPE: Formalin-fixed paraffin embedded; FNA: Fine-needle aspiration; IHC: immunohistochemistry; MSI: Microsatellite instability; TMB: Tumor mutational burden; SNVs: Single-nucleotide variants; Indels: Insertions/deletions; CNAs: Copy number alterations; HLA: Human leukocyte antigen; HRR: Homologous recombination repair; HRD: Homologous recombination deficiency; MHC: Major histocompatibility complex; PARP: Poly-ADP ribose polymerase

For more information about OmniSeq INSIGHT visit **oncology.labcorp.com/omniseq**, or contact your Labcorp Oncology sales representative.

labcorp | Oncology



L26428_BRO. 0125-4